

University of Pennsylvania Carey Law School

## Penn Law: Legal Scholarship Repository

---

Faculty Scholarship at Penn Law

---

2005

### The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation

Catherine T. Struve

*University of Pennsylvania Carey Law School*

Follow this and additional works at: [https://scholarship.law.upenn.edu/faculty\\_scholarship](https://scholarship.law.upenn.edu/faculty_scholarship)



Part of the [Administrative Law Commons](#), [Food and Drug Law Commons](#), [Jurisdiction Commons](#), [Legal Remedies Commons](#), [Litigation Commons](#), [Science and Technology Law Commons](#), and the [Torts Commons](#)

---

#### Repository Citation

Struve, Catherine T., "The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation" (2005). *Faculty Scholarship at Penn Law*. 732.

[https://scholarship.law.upenn.edu/faculty\\_scholarship/732](https://scholarship.law.upenn.edu/faculty_scholarship/732)

This Article is brought to you for free and open access by Penn Law: Legal Scholarship Repository. It has been accepted for inclusion in Faculty Scholarship at Penn Law by an authorized administrator of Penn Law: Legal Scholarship Repository. For more information, please contact [PennlawIR@law.upenn.edu](mailto:PennlawIR@law.upenn.edu).

# The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation

Catherine T. Struve, J.D.\*

## INTRODUCTION

Both the tort system and the FDA seek to protect consumers of medical products. The tort system provides compensation when a consumer is harmed by a defective product and sets incentives for companies to design safer products. The FDA imposes an elaborate system of prior restraint: Pharmaceuticals and some medical devices must undergo extensive testing and stringent risk/benefit analysis before the FDA will approve them for marketing.<sup>1</sup>

Formerly, the FDA viewed its risk/benefit analysis as setting a floor but not a ceiling for product safety: FDA-approved products could be marketed, but the manufacturer might still incur liability if a court later decided that a product was defective or a warning was inadequate.<sup>2</sup> This view has changed in recent years,

---

\* Assistant Professor, University of Pennsylvania Law School. I am grateful to Kristin Madison, Theodore Ruger, William Sage, and Kim Scheppele for their suggestions on the initial stages of this project, to participants in a University of Pennsylvania Law School ad hoc workshop and participants in faculty workshops at Rutgers School of Law-Camden and at Brooklyn Law School, and to Allison Arwady, Stephen Burbank, Rochelle Chodock, Frank Goodman, Geoffrey Hazard, Richard Nagareda, Kermit Roosevelt, Chris Sanchirico, Anthony Sebok, Jonathan Siegel, Allan Stein, Aaron Twerski, and an anonymous reviewer for extremely helpful comments on prior drafts. I thank Dylan Steinberg for superb research assistance and for being a thoughtful sounding board for many of the ideas discussed here, and Ronald Day and the staff of the Biddle Law Library for assistance in obtaining sources. Remaining errors, of course, are mine.

1. See *infra* text accompanying notes 25-43. But see source cited *infra* note 43 (observing that the FDA does not require comparisons between the product under review and alternative treatments).

2. See, e.g., Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997) ("FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."). As Porter—then FDA's Chief Counsel—explained, "FDA regulation of a device cannot anticipate and

however, as policymakers have stressed the need to bring innovative medical treatments to market. Some now argue that the FDA review process should set both a floor and a ceiling: FDA approval of a new product indicates not only that the product can be marketed, but that it should be; FDA rejection of a proposed product warning means not only that the warning is unnecessary, but that it could be counterproductive.

FDA officials who hold this view consider the tort system dangerous. The threat of tort liability, they warn, deters pharmaceutical companies and device makers from developing much-needed new technologies.<sup>3</sup> Even if those innovations are merely delayed rather than abandoned altogether, the cost is felt not merely in financial terms but also in the suffering of people whose illnesses could have been treated with the new drug or device.

These critics argue that the tort system—and juries in particular—should not be permitted to determine product safety. Lay juries, it is claimed, are incapable of understanding the complex scientific and statistical evidence relevant to product safety; they are eager to help injured plaintiffs—especially when the defendant has deep pockets—and they overlook the many consumers who might benefit from the product; they award excessive compensatory damages, especially for pain and suffering; and they often compound the problem by awarding staggering sums in punitive damages.<sup>4</sup> With these concerns in mind, the FDA's then-Chief Counsel took the controversial step, in 2002 through 2004, of submitting amicus briefs in support of the defendants in several cases

---

protect against all safety risks to individual consumers." *Id.*

3. See Amicus Brief at 26, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597) (arguing that tort awards "can harm the public health by retarding research and development and by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments").

4. As the FDA argued last year (with respect to medical devices) in a submission to the United States Court of Appeals for the Third Circuit:

State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population—the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized redetermination of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective.

*Id.* at 25-26.

concerning FDA-approved products.<sup>5</sup> Detailed FDA scrutiny of a product, the briefs contended, should preempt litigation challenging the product's safety (unless the defendant has violated FDA requirements).

There are strong reasons to question the view that FDA approval should preempt products liability claims.<sup>6</sup> To establish that preemption is warranted, proponents should be required to provide convincing evidence of serious flaws in the current system.<sup>7</sup> In this regard, it should be noted that the opponents of the

5. See Amicus Brief for Defendant, *Horn* (No. 02-4597); *Horn*, 376 F.3d at 178 (quoting Statement of Interest of the United States at 7-9, *Murphree v. Pacesetter, Inc.* (Tenn. Cir. Ct. Dec. 12, 2003) (No. 005429-00-3)); Amicus Curiae Brief of the United States, in Support of Defendants/Respondents, *Dowhal v. Smithkline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2003) (No. S109306); Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2002) (Nos. 02-55372, 02-55498).

Concerns over the FDA's stance arose partly from reports that the FDA's Chief Counsel solicited input from industry lawyers concerning cases in which the FDA could usefully intervene on behalf of defendants. In December 2003, then-FDA Chief Counsel Daniel Troy participated in a "roundtable" entitled "The Case for Preemption" at a continuing legal education conference designed for in-house and outside counsel for pharmaceutical and medical device companies. Program, 8th Annual Conference for In-House Counsel and Trial Attorneys: Drug and Medical Device Litigation (Dec. 14-16, 2003), <http://www.gibbonslaw.com/publications/uploadedfiles/602L04-NYC.pdf>.

Jessica Dart, who represents a number of products liability plaintiffs, attended the conference after learning that the roundtable agenda included two of her cases. Affidavit of Jessica R. Dart at ¶¶ 1, 3, *Dusek v. Pfizer, Inc.*, No. Civ. A. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004). According to Dart, Troy "made it clear that he was interested in filing even more amicus briefs on behalf of pharmaceutical manufacturers and actually invited his defense counsel audience to approach him with requests . . . ." *Id.* ¶ 5.

Daniel Troy resigned from his post as Chief Counsel in November 2004. See FDA, Statement of Dr. Lester M. Crawford, Acting Commissioner of Food and Drugs on the Resignation of Daniel E. Troy (Nov. 16, 2004), <http://www.fda.gov/bbs/topics/news/2004/NEW01135.html>. News reports, however, have suggested that the FDA's Acting Commissioner continues to support Troy's policy views. See, e.g., *FDA Chief Counsel Dan Troy Resigning, Masoudi Rumored as Replacement*, FDA WEEK, Nov. 19, 2004 (quoting an internal email from Lester Crawford that praised Troy for "put[ting] his personal reputation on the line defending the Agency's prerogatives from intrusion by courts applying state law in product liability actions").

6. For a summary of current law concerning preemption, see *infra* notes 105-110 and accompanying text.

7. The tort system is designed to promote product safety and compensate those injured by defective products—roles that were entirely compatible with the FDA's previous view that tort liability could supplement the FDA's efforts to ensure product safety. See *supra* note 2 and accompanying text. Moreover, products liability law lies within the area of consumer health and safety—an area traditionally within the regulatory powers of the states. Therefore, those who assert

tort system overstate the case.<sup>8</sup> Empirical data indicate that juries do better than their critics assert at handling technical issues,<sup>9</sup> that juries are not as eager as some think to award damages against business defendants,<sup>10</sup> and that punitive damages are awarded rarely in products liability suits (and mainly in cases involving egregious misbehavior).<sup>11</sup>

In addition to demonstrating a need for change, advocates of preemption should also be required to demonstrate that preemption is the best alternative to the status quo. It is true that the FDA possesses greater expertise concerning

that Congress should preempt state tort liability should bear the burden of showing that such preemption is necessary.

8. Theodore Eisenberg and James Henderson have argued that, in fact, data indicate a pro-defendant trend in recent decades. See Theodore Eisenberg & James A. Henderson, Jr., *Inside the Quiet Revolution in Products Liability*, 39 UCLA L. REV. 731, 741 (1992) (noting “a continuing decline in plaintiff success rates” over the period from 1979 to 1989); Theodore Eisenberg, *Judicial Decisionmaking in Federal Products Liability Cases, 1978-1997*, 49 DEPAUL L. REV. 323, 323-24 (1999) (noting low plaintiff win rates at trial and also observing that “[o]f those cases that survive early pretrial skirmishing, and end in pretrial judgment, an increasing percentage is resulting in pretrial judgment in favor of defendants” based on data extending “through fiscal 1997”).

9. See, e.g., NEIL VIDMAR, *MEDICAL MALPRACTICE AND THE AMERICAN JURY: CONFRONTING THE MYTHS ABOUT JURY INCOMPETENCE, DEEP POCKETS, AND OUTRAGEOUS DAMAGE AWARDS* 265 (1995); Joe S. Cecil et al., *Citizen Comprehension of Difficult Issues: Lessons from Civil Jury Trials*, 40 AM. U. L. REV. 727, 729 (1991).

10. See VALERIE P. HANS, *BUSINESS ON TRIAL: THE CIVIL JURY AND CORPORATE RESPONSIBILITY* 23, 175-77 (2000). Other researchers have noted that plaintiffs’ win rates are relatively low in products liability jury trials (compared to other types of cases). See Theodore Eisenberg et al., *Litigation Outcomes in State and Federal Courts: A Statistical Portrait*, 19 SEATTLE U. L. REV. 433, 437 (1996) (reporting with respect to products liability claims (other than asbestos claims) tried in 1991-1992 that “success rates are 40 percent in state court and 37 percent in federal court”). Of course, this finding does not prove that juries are particularly unsympathetic to products liability plaintiffs; the mix of cases selected for trial can differ across types of cases and can affect win rates. However, the finding does suggest that juries are not automatically receptive to plaintiffs’ claims in products liability cases.

11. See, e.g., Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1, 23 (1992) (describing a study of products liability verdicts that indicated that “punitive damages were rarely awarded,” which showed that “[t]he gap between what was awarded and collected was great,” and that cases resulting in punitive awards involved “corporate misconduct and serious injuries”). Researchers recently summarized the empirical findings on punitive awards: “Contrary to popular belief, juries rarely award such damages, and award them especially rarely in products liability and medical malpractice cases. Rather, juries tend to award punitive damages in intentional misconduct cases. When juries do award punitive damages, they do so in ways that relate strongly to compensatory awards.” Theodore Eisenberg et al., *Juries, Judges, and Punitive Damages: An Empirical Study*, 87 CORNELL L. REV. 743, 745 (2002) (footnotes omitted).

product safety than a civil jury. The FDA is correct to suggest that FDA regulation and the tort system should not operate entirely independently; the FDA's expertise gives its views on product safety considerable authority and those views should play a role in assessing product liability. But I will argue that even if systemic change is shown to be necessary, allowing FDA regulation to supplant the tort system is not the only, or the best, solution.

Permitting FDA approval to preclude the possibility of tort liability does more than ensure that product safety decisions are reserved to the FDA. Preemption of tort litigation removes the opportunity for litigation to aid the FDA in its goal of monitoring product safety.<sup>12</sup> Preemption also denies compensation to persons harmed by an FDA-approved product—even if they were harmed after a safety problem first surfaced but before the FDA took regulatory action to remove the product from the market or to require additional warnings.<sup>13</sup>

There exists a large body of literature concerning the appropriate scope of FDA regulatory preemption.<sup>14</sup> I will argue, however, that this literature fails to contemplate the full range of possible options.<sup>15</sup> Even if proponents of reform can ultimately carry their burden of showing the need for change, policymakers

12. See Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2069 (2000) (“[I]f we are substantially dependent on the tort system to provide the educational function of revealing massive cover-ups of health information by industries like asbestos, or occasional efforts to conceal risk information from regulatory agencies like the FDA, then it is undeniably the case that tort law is serving a positive function of some consequence.”).

13. Plaintiffs could, under some circumstances, assert a claim against the United States based upon the FDA's failure to act concerning a product, but such claims would often fail due to the “discretionary function” exception in the Federal Tort Claims Act. See *Berkovitz v. United States*, 486 U.S. 531, 545 (1988) (stating that “application of the discretionary function exception” to a claim concerning agency determinations that a vaccine complied with federal standards “hinges on whether the agency officials making that determination permissibly exercise policy choice”).

14. See, e.g., Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994); Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181 (1991); Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187 (1993); Brian J. Donato & Mary Beth Neraas, *Federal Preemption of Product Liability Claims Involving Drugs and Medical Devices Regulated Under the Federal Food, Drug, and Cosmetic Act*, 48 FOOD & DRUG L.J. 305 (1993); David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395 (1996); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559 (1997); Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183 (1994).

15. Cf. Richard A. Nagareda, *In the Aftermath of the Mass Tort Class Action*, 85 GEO. L.J. 295, 298 (1996) (arguing that “the debate over procedural reform within the tort system ignores the relationship between that system and the modern administrative state”).



should keep in mind that preemption is not the only alternative to the status quo. In addition to considering whether there are ways to improve the performance of the current litigation system, policymakers should ask whether litigation could be restructured in a way that could improve the FDA's regulatory performance.

This Article considers whether Congress could create structural links between the litigation system and the FDA—either by providing for agency adjudication of products liability claims or by requiring federal courts to refer issues of product safety and causation to the agency for determination. After comparing four possible configurations, I conclude that policy considerations would weigh in favor of adjudication in federal court, with referral of technical questions to the FDA. In discussing this possibility, I draw upon insights provided by Richard Nagareda, who has argued that such a referral could be accomplished through the use of the primary jurisdiction doctrine.<sup>16</sup> I conclude, however, that such a mechanism could well violate the Seventh Amendment if applied to private products liability claims.<sup>17</sup> Accordingly, I describe an alternative scheme in which product safety claims for damages by the United States as *parens patriae*<sup>18</sup> could be litigated in federal court by *qui tam* relators.<sup>19</sup>

The system would employ a somewhat novel process to adjudicate claims. After a period of discovery, a suit that survived summary judgment would proceed to a bench trial. Instead of ruling upon the issues of product safety and causation, however, the judge would refer those issues to an FDA advisory panel. The panel's determinations would be reviewed by the FDA, and the FDA's final determinations would be conclusive regarding product safety and causation.<sup>20</sup> If warranted, the court would then determine an aggregate amount of damages and would enter judgment. A fraction of the damages would be paid to the *qui tam* relator, and the bulk of the damages would finance a federal compensation fund

---

16. See *id.* at 352 (suggesting that Congress enact a framework within which courts would “apply the doctrine of primary jurisdiction to defer their disposition of individual claims pending agency action”); see also Richard A. Nagareda, *Turning from Tort to Administration*, 94 MICH. L. REV. 899, 978 (1996) (suggesting a regulatory scheme for facilitating claim resolution, within which “[a] mass tort centered upon a medical device like breast implants appropriately might come within the expertise of the FDA—the agency that originally licensed that product”).

17. See *infra* notes 238-265 and accompanying text.

18. This phrase, which translates “parent of the country,” denotes the state's ability to sue to protect its interest in the health and safety of its citizens. See *infra* notes 153-157 and accompanying text.

19. *Qui tam* relators are litigants who sue on behalf of the government (and who may earn a bounty for doing so successfully). See *infra* notes 158-170 and accompanying text.

20. The FDA's findings would be reviewed in the federal court proceeding for compliance with procedural requirements and to ensure that the findings were supported by some evidence. See *infra* notes 143-151 and accompanying text.

for those harmed by the product.<sup>21</sup>

Such a mechanism might improve the FDA's postmarketing surveillance of regulated products. The filing of such a suit could flag possible safety problems for the FDA. Discovery obtained in such a suit might uncover evidence that had not been reported to the FDA, or upon which the FDA had not yet focused. And the FDA's review of panel determinations would provide the agency with an opportunity to reassess its product safety determinations in light of the record developed in the litigation.

The scheme would also change the landscape of compensation. The amount of damages awarded could vary depending on the presence and degree of fault on the part of the company: A carelessly overlooked safety problem could trigger compensatory damages, while instances of willful deception might generate additional penalties. Even in the absence of fault, the scheme might require the company to provide some minimum level of damages to compensate for harms traceable to the product. Damages awarded in such a scheme would likely be smaller than some jury awards in similar cases tried in the tort system. On the other hand, damages could be recovered in cases where suits would currently be preempted, as well as in cases where preemption would not exist but where state law would not impose liability.

Companies could choose whether or not to opt in to the new system; if they declined to opt in, there would be no preemption of state-law tort claims. The opt-in feature would have an interesting policy implication.<sup>22</sup> Though preemption advocates argue that the size and variability of jury awards deter companies from pursuing desirable projects, that assertion is hotly contested and difficult to evaluate. Companies themselves are better suited than legislators to determine the incentive effects of litigation, but their statements are likely to be self-interested. By permitting companies to choose between the tort system and the new alternative, the scheme would elicit a more accurate picture of companies' preferences.

My argument proceeds in four steps. I begin by summarizing, in Part I, the FDA's role in scrutinizing product safety. Part I explains why premarketing review predictably will fail to identify all potential safety issues and discusses flaws in the FDA's current postmarketing surveillance system. In Part II, I consider several possible structural changes that could link litigation more closely to the regulatory process. After weighing the relative merits of agency and court adjudication, and comparing the types of entities that might press a claim concerning product safety, I suggest that *qui tam* suits on behalf of the

---

21. See *infra* notes 168-169, 176-178 and accompanying text.

22. Companies' ability to choose whether or not to opt in to the system also addresses some possible constitutional concerns about the scheme. See *infra* note 268 and accompanying text.



United States as *parens patriae*, litigated in federal court, might be the best option for creating structural links. Part III considers the advantages of the system's opt-in feature and argues that the system could supplement and improve the FDA's postmarketing surveillance efforts. In conclusion, I consider potential disadvantages of the system—including the possibility that a pro-industry bias or a lack of resources might compromise the agency's role in the proposed scheme—and I assess the place of the hybrid scheme in the debate over preemption. While this Article does not establish that the hybrid scheme is superior to the status quo, it does support the contention that the hybrid scheme is superior to preemption. Advocates of preemption, then, not only must demonstrate that the current system is undesirable, but also should be required to show that preemption is preferable to a hybrid system.

## I. THE ROLE OF POSTMARKETING SURVEILLANCE IN THE REGULATORY SYSTEM

An FDA task force recently summarized the agency's role in promoting consumer safety:

The Agency establishes and enforces product quality standards intended to prevent defective products from reaching the market. For products of acceptable quality, the central element of FDA's risk management is controlling product entry to the marketplace. The majority of FDA program resources are devoted to premarketing scientific risk identification and assessment and approval or nonapproval. Significant, but substantially fewer, resources are devoted to postmarketing surveillance and risk assessment activities.<sup>23</sup>

In this Section I explain why postmarketing surveillance is critical to consumer safety, and I argue that despite the FDA's efforts to improve postmarketing surveillance, that aspect of its program still falls short.

### *A. Premarket Scrutiny*

During premarket review, the FDA weighs a medical product's known risks and determines whether the product should be approved for marketing and, if so, whether warnings should be included in the labeling.<sup>24</sup> New drugs and medical devices undergo varying degrees of FDA scrutiny depending on their originality and other factors.

---

23. TASK FORCE ON RISK MGMT., FDA, MANAGING THE RISKS FROM MEDICAL PRODUCT USE—CREATING A RISK MANAGEMENT FRAMEWORK 29-30 (1999), <http://www.fda.gov/oc/tfrm/riskmanagement.pdf> [hereinafter RISK MANAGEMENT REPORT].

24. *Id.* at 30.

The standard drug approval proceeds in four steps:

Phase I seeks pharmacologic effects information and early evidence on effectiveness in several dozen healthy persons. Phase II measures several hundred closely monitored sick patients for the clinical effectiveness of the drug. Both prepare the product for its real test, the multiple Phase III effectiveness and safety tests which form the basis for risk assessments and label warnings, during which more than a thousand patients are likely to be exposed.

The final phase of the review process leads to formal acceptance of the proposed [new drug application].<sup>25</sup>

The process is lengthy; approval can be somewhat speedier, however, for certain urgently needed drugs and for generic versions of drugs already on the market.<sup>26</sup> A “fast track” approval process is available for new drugs that “treat[] a serious or life-threatening condition and . . . demonstrate[] the potential to address unmet medical needs for such a condition.”<sup>27</sup> Manufacturers of generic drugs can take advantage of the abbreviated new drug application process,<sup>28</sup> often bypassing “the extensive clinical testing that a pioneer product would endure.”<sup>29</sup>

Medical devices are grouped in three categories, in ascending order of riskiness. In Class I are seemingly innocuous devices such as dental floss;<sup>30</sup> these receive the least demanding regulatory oversight.<sup>31</sup> Devices whose safety and

25. 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 13.11, at 13-66 to -67 (2d ed. 1995).

26. See James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 304 (2003) (“The FDA approval process is complex and detailed, and its timing cannot keep up with the fast pace of medical discovery about pharmaceutical benefits. Even with the advent of the accelerated ‘fast-track’ approval process, the process for drug approval is one that is still lengthy and time-consuming.” (footnote omitted)).

27. 21 U.S.C. § 356(a)(1) (2000); see also 21 C.F.R. § 314.500 (2004). For drugs that receive fast track evaluation, the FDA may impose safety restrictions on the distribution or use of the drug, see *id.* § 314.520, and may require postapproval studies, see *id.* § 314.510, and “[p]ostapproval reporting of adverse events is much more closely monitored,” 1 O'REILLY, *supra* note 25, § 13.13, at 13-83.

28. See 21 C.F.R. § 314.92 (2004).

29. 1 O'REILLY, *supra* note 25, § 13.15, at 13.93.

30. See 21 C.F.R. § 872.6390 (2004).

31. See *id.* § 860.3(c)(1) (“Class I means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and

effectiveness require greater scrutiny—such as contact lenses<sup>32</sup>—are grouped in Class II and subjected to additional controls.<sup>33</sup> When more study is needed to determine the safety and effectiveness of a medically important or potentially dangerous device, it is assigned to Class III and the manufacturer must obtain premarket approval from the FDA.<sup>34</sup>

A company seeking premarket approval of an innovative Class III device must test the product and must provide detailed data, including “full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective.”<sup>35</sup> However, an applicant can use “premarket notification” to bypass the full premarket application process if it can show that its device is “substantially equivalent” to a device already on the market.<sup>36</sup> Though a premarket notification applicant will need to submit an analysis of existing data on the device, the FDA will not usually demand testing.<sup>37</sup> If the FDA accepts the notification, it will approve the product for marketing; if not, the applicant will have to proceed to the premarket application.

The FDA’s mission of protecting consumer safety dictates rigorous premarketing review, but its mandate to foster innovation creates a countervailing pressure. In 1997, finding that “prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health,”<sup>38</sup> Congress directed the FDA to employ the “least burdensome”

reports), and 520 (general provisions) of the act.”).

32. *See id.* § 886.5916(b)(1) (stating that daily wear rigid gas permeable contact lenses are Class II devices); *id.* § 886.5925(b)(1) (stating that daily wear soft contact lenses are Class II devices).

33. *See id.* § 860.3(c)(2) (“A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including . . . performance standards, postmarket surveillance, patient registries, . . . guidance documents . . . , recommendations, and other appropriate actions . . .”).

34. The regulations explain:

A device is in class III if insufficient information exists to determine that general [or special] controls are sufficient to provide reasonable assurance of its safety and effectiveness . . . and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

*Id.* § 860.3(c)(3).

35. 21 U.S.C. § 360e(c)(1)(A) (2000).

36. *See id.* § 360e(b)(1)(B).

37. *See* 1 O’REILLY, *supra* note 25, § 18.07, at 18-32.

38. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 101(1), 111 Stat. 2296, 2298 (reprinted at 21 U.S.C. § 379g note (2000)).

methods of evaluating products in the premarket notification and premarket approval processes.<sup>39</sup> Pursuant to this mandate, the FDA has declared that premarket approval can sometimes be based on “well-designed bench and/or animal testing” rather than clinical tests.<sup>40</sup> Moreover, the FDA will consider the extent to which measures such as postmarketing trials can substitute for premarket scrutiny.<sup>41</sup> Though clinical data are in any event not required for most premarket notifications, the FDA responded to the “least burdensome” directive by emphasizing that “substantial equivalence” determinations should also be streamlined.<sup>42</sup>

Though the details of the approval process are complex, the bottom line is plain: When a company seeks FDA approval of an innovative drug or Class III device, the FDA will require the manufacturer to submit test data concerning safety and effectiveness. The FDA will weigh the product’s potential risks and benefits in determining whether to grant approval,<sup>43</sup> and consideration of the product’s risks can lead the agency to impose detailed requirements concerning product warnings. Premarketing scrutiny can provide a significant increase in product safety, but, as the next Section discusses, there is no way that it can discern all potential risks.<sup>44</sup>

---

39. 21 U.S.C. § 360c(a)(3)(D)(ii) (2000) (premarket approval); *id.* § 360c(i)(1)(D) (premarket notification).

40. FDA, THE LEAST BURDENSOME PROVISIONS OF THE FDA MODERNIZATION ACT OF 1997: CONCEPT AND PRINCIPLES; FINAL GUIDANCE FOR FDA AND INDUSTRY 10 (2002), <http://www.fda.gov/cdrh/ode/guidance/1332.pdf>.

41. *See id.* at 4.

42. *See id.* at 9.

43. However, the FDA does not require comparative testing of the product’s performance relative to competitor brands (though marketing or practical considerations may dictate that the company perform such tests). *See* Editorial, *Comparing Prescription Drugs*, N.Y. TIMES, Aug. 27, 2003, at A20 (“[T]he drugs used in this country are seldom tested against one another in head-to-head combat. Instead, each is tested separately against a placebo and then, if shown to be safe and effective, is approved for marketing.”).

44. Even as to risks that could be discerned at the premarket review stage, some have argued that the FDA’s reliance on the regulated company to supply the necessary safety data can lead to problems. *See, e.g.,* Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 559 (2002) (“When the onus is on the regulatee to provide data establishing that its product is ‘safe and effective’ . . . , the temptation is strong for a company to discount data indicating that the product may not meet the statutory test.”).

*B. The Need for Postmarketing Surveillance*

Even if it is rigorously conducted,<sup>45</sup> a process that focuses on prior approval inevitably will fail to capture all relevant information.<sup>46</sup> Clinical trials normally will fail to reveal a number of types of problems:<sup>47</sup> those that occur relatively

---

45. There is some reason to question whether the current premarketing approval process is always sufficiently rigorous. Results of a 2002 survey of FDA scientists revealed that of the 360 recipients who responded to the question, "Have you ever been pressured to approve or recommend approval for an NDA despite reservations about the safety, efficacy, or quality of the drug?," eighteen percent responded "Yes." OFFICE OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., HHS SURVEY, at question 25 (2002), [http://www.peer.org/docs/fda/12\\_14\\_04\\_FDA\\_survey.pdf](http://www.peer.org/docs/fda/12_14_04_FDA_survey.pdf) [hereinafter HHS SURVEY]. The results to some of the survey questions, which were made public pursuant to a request under the Freedom of Information Act (FOIA), are available at [http://www.peer.org/docs/fda/12\\_14\\_04\\_FDA\\_survey.pdf](http://www.peer.org/docs/fda/12_14_04_FDA_survey.pdf); see also News Release, Pub. Employees for Env'tl Responsibility, FDA Scientists Issued Early Warnings on Drug Approvals (Dec. 16, 2004), [http://www.peer.org/news/news\\_id.php?row\\_id=449](http://www.peer.org/news/news_id.php?row_id=449) (stating that the survey results were obtained under FOIA). Health and Human Services researchers estimated that 846 Center for Drug Evaluation and Research reviewers were eligible to participate in the survey; 401 responses were received. See OFFICE OF INSPECTOR GEN., DEP'T HEALTH & HUMAN SERVS., FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW 37 app. F (2003), <http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf>. The researchers noted "three main limitations" of their survey: The survey used web-based technology and technical difficulties may have caused some "non-responses"; though the survey was anonymous, "some respondents may not have participated out of concerns for their anonymity"; and "although survey access was limited to CDER employees, the potential exists that some individuals not in our intended population completed the survey." *Id.*

46. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 496 (1997) (discussing "the inability of the [investigational new drug] testing process to identify all of the risks associated with use of a drug"); William M. Sage, Note, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 990 (1988) (noting with respect to drugs that "extensive use in humans is the only way to measure safety or efficacy").

47. This is true even if the trial is designed and executed evenhandedly and in good faith. Some observers, however, assert that "bias is now rampant in drug trials." MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 106 (2004). Angell notes a number of strategies that can skew study results; one is "to enroll only young subjects in trials . . . . Because young people experience fewer side effects, drugs will look safer in these trials than they would in practice." *Id.* at 107-08. Results of a 2002 survey of FDA scientists reveal doubts about the sufficiency of the information provided in new drug applications. Three hundred and sixty-one survey recipients responded to the question "[H]ow often do NDAs, including amendments submitted during the PDUFA time clock, contain enough data to adequately assess the SAFETY of a drug?" While fifty-six percent responded "Most of the time," thirty-two percent responded "Some of the time" (the other options were "All of the time" (two percent),

rarely,<sup>48</sup> those involving relatively subtle increases in the risk of already common problems, those that disproportionately affect a population subset not represented in the trial,<sup>49</sup> and those with a long latency period.<sup>50</sup> Thus, “premarketing studies cannot guarantee product safety.”<sup>51</sup>

Though some problems may surface almost immediately after marketing commences,<sup>52</sup> others may take years to appear.<sup>53</sup> Once problems do manifest themselves, however, it is critical for the FDA to recognize and respond to those problems promptly, so as to minimize the danger to consumers.<sup>54</sup> An official from the General Accounting Office has suggested that there is growing cause for concern:

“Rarely” (nine percent), and “Never” (two percent)). Eighty-seven percent (out of 354 respondents) stated that “additional SAFETY data [would] improve CDER’s ability to adequately assess the safety of a drug” at least “[t]o some extent.” HHS SURVEY, *supra* note 45, at questions 12, 13.

48. See Funmilayo O. Ajayi et al., *Adverse Drug Reactions: A Review of Relevant Factors*, 40 J. CLINICAL PHARMACOLOGY 1093, 1094 (2000) (“Most clinically relevant [adverse drug reactions] occur at a rate of 1 in 10,000 or less.”).

49. See Ajayi et al., *supra* note 48, at 1094 (“[A] major shortcoming of clinical trials can be the failure to account for variability among patients in terms of age, gender, genetic background, coadministered drugs, the coexistence of other diseases, and their concurrent effects on drug metabolism and/or excretion.”); Am. Med. Ass’n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA’s Council on Ethical and Judicial Affairs*, 49 FOOD & DRUG L.J. 359, 359-60 (1994) [hereinafter *AMA Report*] (noting that “the patient population used in clinical trials does not usually include vulnerable populations such as the elderly, the young, women, those with complicated disease, or those taking other medications”).

50. See, e.g., Timothy Brewer & Graham A. Colditz, *Postmarketing Surveillance and Adverse Drug Reactions: Current Perspectives and Future Needs*, 281 JAMA 824, 824 (1999) (noting that “[p]remarketing trials . . . lack the follow-up necessary to detect [adverse drug reactions] widely separated in time from the original use of the drug or delayed consequences associated with long-term drug administration”).

51. *AMA Report*, *supra* note 49, at 359-60.

52. See *Examining the Incidence of Medical Errors, Focusing on Understanding Adverse Drug Events: Hearing Before the Senate Comm. on Health, Educ., Labor, & Pensions*, 106th Cong. 6 (2000) [hereinafter *Senate Medical Errors Hearing*] (statement of Dr. Janet Woodcock, Director, Ctr. for Drug Evaluation and Research, FDA) (“New types of risks, and rare risks, may well be uncovered in the first year a drug is on the market.”).

53. See Ajayi et al., *supra* note 48, at 1099 (suggesting that “approximately 2 to 3 years of postmarketing experience is required to fully understand the safety profile of a new drug”).

54. Cf. Alastair J. J. Wood, *The Safety of New Medicines: The Importance of Asking the Right Questions*, 281 JAMA 1753, 1753 (1999) (discussing five drugs withdrawn from the market, and stating that “a staggering 19.8 million patients . . . were estimated to have been exposed to these 5 drugs before their removal”); Ajayi et al., *supra* note 48, at 1094 (“The [adverse drug reactions] undetected prior to approval of a drug product may pose serious health threats once released into the general population . . .”).



[T]he pressures on the U.S. system of pharmaceutical risk management are increasing. Prescription drug use in the U.S. continues to increase; . . . roughly 10 prescriptions were filled for every American in 1998. Further, direct-to-consumer advertising and other marketing techniques can greatly accelerate the rate at which a new drug is prescribed to large numbers of patients.<sup>55</sup>

Other recent changes also serve to raise the stakes: It is now more likely that a drug will enter the U.S. market before it has developed a track record abroad and that it will do so on the basis of a less searching "fast track" review by the FDA.<sup>56</sup> Postmarketing surveillance, then, must play an increasingly vital role in ensuring consumer safety;<sup>57</sup> but as the next Section discusses, the available resources fall short.<sup>58</sup>

### *C. Deficiencies in the FDA's Postmarketing Surveillance*

The goals of the FDA's postmarketing surveillance are "to detect adverse events not previously observed, improve understanding of the potential severity of previously unanticipated risks, detect events resulting from drug interactions or drug effects in particular populations, and assess the potential for causal relationships."<sup>59</sup> The FDA employs several different methods, including reporting systems, medical databases, and studies and registries focused on

---

55. *Senate Medical Errors Hearing*, *supra* note 52 (letter from Janet Heinrich, Associate Director, Health Fin. & Pub. Health Issues, U.S. Gen. Accounting Office, to the Honorable James M. Jeffords, Chairman, Sen. Comm. on Health, Educ., Labor, & Pensions).

56. As Marcia Angell has explained:

[U]ntil a decade ago, drugs were usually first approved in Europe . . . . But now, most drugs are approved first in the United States. Furthermore, an increasing number of them are given accelerated review by the FDA, which means they come to market on the basis of less evidence. Thus, a drug may come into widespread use with very little research to back it up, and no experience in another country.

ANGELL, *supra* note 47, at 162.

57. See Ajayi et al., *supra* note 48, at 1097 ("Although fraught with certain limitations such as underreporting, the use of postmarketing surveillance is still very critical in collecting data on drug safety because the true adverse reaction profile of a drug is often not revealed until it has been widely used."); Sage, *supra* note 46, at 1015 ("At the time a drug is approved, many adverse effects are undiscoverable. Though the first such ADRs to arise are unpreventable, effective postmarketing surveillance can greatly reduce the total damage.").

58. See *Senate Medical Errors Hearing*, *supra* note 52 (statement of Sen. Edward M. Kennedy) ("Approximately 48 percent of prescription drugs on the market today have become available only since 1990. FDA needs additional resources to identify adverse reactions . . . ."); Green, *supra* note 46, at 495-96 (noting with respect to "the post-approval period" concerning new drugs that "the FDA has inadequate resources to enforce regulatory compliance").

59. RISK MANAGEMENT REPORT, *supra* note 23, at 52.

specific issues.<sup>60</sup> Although the FDA publicly takes a generally positive view of its own efforts,<sup>61</sup> there are reasons to question the agency's effectiveness. Indeed, a 2002 internal survey of reviewers in the FDA's Center for Drug Evaluation and Research (CDER) found that some two-thirds of respondents were either "[n]ot at all confident" or only "[s]omewhat confident" that the CDER "adequately monitors the safety of prescription drugs once they are on the market."<sup>62</sup> These concerns are well-founded: The FDA receives large amounts of data both from regulated companies and from healthcare providers, but those data will sometimes be incomplete or lack sufficient detail. Further, the FDA does not have the capability—or, some charge, the motivation—to analyze thoroughly and act swiftly upon all the information that it does receive.

Federal law imposes significant reporting duties on manufacturers of medical devices,<sup>63</sup> as well as on certain healthcare facilities where those devices are used ("user facilities").<sup>64</sup> Manufacturers must report deaths, serious injuries, and device malfunctions, as well as baseline data, to the FDA within set time periods. User facilities must also report deaths to the FDA, and must report serious injuries to the manufacturer.<sup>65</sup> Pharmaceutical companies have similar reporting duties with respect to adverse drug events.<sup>66</sup>

---

60. *Id.* at 54. An FDA task force recently listed these methods:

spontaneous reporting systems to rapidly identify potential new problems; large healthcare databases with product use linked to subsequent diagnoses, hospitalizations, and other adverse events; cohort and case-control studies conducted as needed to investigate a specific safety issue in depth; and registries initiated when potential risks (particularly those apparent only with long-term follow-up) are sufficient to warrant identification and active follow-up of individuals exposed to a product.

61. *See id.* at 51 ("The Task Force believes that FDA's postmarketing surveillance and risk assessment programs are, for the most part, accomplishing the purposes for which they were designed.").

62. HHS SURVEY, *supra* note 45, at question 45. Twenty-eight percent of respondents were "[m]ostly confident" and six percent of respondents were "[c]ompletely confident." *Id.*

63. *See* 21 U.S.C. § 360i(a) (2000) (imposing reporting requirements on manufacturers and importers of medical devices); 21 C.F.R. § 803.10(c) (2004) (summarizing device manufacturers' reporting requirements).

64. *See* 21 U.S.C. § 360i(b) (2000) (imposing reporting requirements on "device user facilities").

65. *See* 21 C.F.R. § 803.10 (2004) (summarizing user facilities' reporting duties).

66. *Id.* § 314.80 (specifying reporting requirements regarding adverse drug experiences). As Barbara Noah has explained:

Within fifteen days, manufacturers must submit reports of all adverse drug experiences that are both "serious" and "unexpected" and they must "promptly investigate" all such adverse experiences. By contrast, manufacturers need only submit periodic reports for non-serious or expected adverse events. The periodic reports must contain summaries of

Potential tort liability (where it exists) and the possibility of FDA penalties give companies incentives to monitor and report adverse events.<sup>67</sup> But there are countervailing pressures as well: As three government researchers recently noted, “[t]here are strong disincentives for companies . . . to identify safety problems with licensed drugs quickly and efficiently . . . . [S]eeking out and sharing bad news about a product are unlikely to increase business.”<sup>68</sup> Commenting on “episodes of falsification and concealment of research by manufacturers,” William Sage has observed that “[s]ince a manufacturer may have invested several million dollars in a drug before a single adverse reaction is reported, this misbehavior is predictable albeit unforgiveable.”<sup>69</sup> In a reflection of these pressures, there are indications that Merck was aware of potential problems with Vioxx long before it withdrew the drug from the market in September 2004, and that the company may have attempted to retard the spread of information concerning such safety concerns.<sup>70</sup>

---

all fifteen-day reports, along with reports of other adverse experiences, and explanations of any action that the manufacturer has taken in response to reported information.

Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data To Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 470-71 (2000) (citing 21 C.F.R. § 314-80 (1999)). Noah notes that manufacturers of new drugs incur additional reporting obligations:

The regulations also require that holders of an approved [new drug application] submit quarterly adverse drug experience reports for the first three years of marketing and annual reports afterwards . . . . Finally, additional regulations for new drugs require that manufacturers submit a brief summary of new information accumulated during the preceding year that “might affect the safety, effectiveness, or labeling of the drug product” along with a description of the manufacturer’s intended response to this information.

*Id.* at 471 (citing 21 C.F.R. §§ 314-80 to -81 (1999)).

67. See Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 35 (1991) (noting that “there are severe regulatory and other penalties” for violating FDA’s reporting rules, and that “product liability pressure . . . pushes in the direction of reporting everything that could conceivably be reported as an [adverse drug reaction] and making sure it shows up in the labeling”).

68. Marie R. Griffin et al., *Commentary: Postmarketing Surveillance for Drug Safety: Surely We Can Do Better*, 75 CLINICAL PHARMACOLOGY & THERAPEUTICS 491, 492 (2004). The authors are investigators at the Centers for Education and Research on Therapeutics. See *id.* at 494.

69. Sage, *supra* note 46, at 1019-20; cf. Green, *supra* note 46, at 488 (noting that “the pharmaceutical industry’s history is littered with instances of deliberate or negligent withholding of information from the FDA in the new drug approval process”).

70. See, e.g., Gardiner Harris, *F.D.A. Failing in Drug Safety, Official Asserts*, N.Y. TIMES, Nov. 19, 2004, at A1 (noting the existence of documents in which “Merck executives and scientists discussed the possible link between Vioxx and heart damage years before the company publicly

The FDA also relies upon health professionals to identify potential problems. To this end, it created the MedWatch program, which solicits reports from health professionals regarding deaths or serious injuries associated with drugs, medical devices or other regulated products;<sup>71</sup> reports received through this program are evaluated and entered into databases.<sup>72</sup> The system, however, is plagued by underreporting.<sup>73</sup> For one thing, doctors may notice unexpected harms, but they are less likely to discern an increase in the probability of familiar harms.<sup>74</sup> For another, doctors may be unwilling to report events that might get them into trouble.<sup>75</sup> (As some medical devices are marketed for use outside of medical settings, the likelihood of spontaneous reporting decreases still further.<sup>76</sup>)

---

admitted that the drug could cause harm”); Anna Wilde Mathews & Barbara Martinez, *Warning Signs: E-mails Suggest Merck Knew Vioxx’s Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1 (stating that “internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug’s commercial prospects”); Barry Meier, *Questions Are Seen on Merck’s Stance on Pain Drug’s Use*, N.Y. TIMES, Nov. 24, 2004, at A1 (stating that Merck was aware, “as far back as 2001,” that Vioxx might not provide gastrointestinal benefits for older users who were also taking aspirin regularly, and that Merck “never followed up with a plan in 2001 to run a definitive test about the drug’s advantages, if any, to aspirin users”).

71. See Brewer & Colditz, *supra* note 50, at 825.

72. See RISK MANAGEMENT REPORT, *supra* note 23, at 54-55 (discussing Adverse Event Reporting System database for drugs and biological products); *id.* at 58 (discussing the Manufacturer and User Device Experience database for medical devices).

73. See U.S. GEN. ACCOUNTING OFFICE, ADVERSE EVENTS; SURVEILLANCE SYSTEMS FOR ADVERSE EVENTS AND MEDICAL ERRORS: STATEMENT OF JANET HEINRICH 3 (2000), <http://www.gao.gov/archive/2000/he00061t.pdf> (noting that the “FDA believes that its . . . Adverse Event Reporting System . . . receives reports for only about 1 to 10 percent of all [adverse drug events]”); Brewer & Colditz, *supra* note 50, at 825 (“[S]erious adverse events that may represent [adverse drug reactions] are underreported by physicians to either manufacturers or the FDA.”);

74. See Brewer & Colditz, *supra* note 50, at 825 (“Unusual . . . events that occur during initial or long-term drug use are more likely to be detected by case reports than increases in common events or events that occur remotely in time from the medication use.”); Griffin et al., *supra* note 68, at 492 (noting that “voluntary reports are less likely to be helpful in determining whether a drug causes or increases the severity of a condition that is relatively common in the background population”).

75. See Roxana Mehran et al., *Post-Market Approval Surveillance: A Call for a More Integrated and Comprehensive Approach*, 109 CIRCULATION 3073, 3074 (2004) (“[P]hysicians encountering adverse events while performing off-label procedures may be reluctant to call undue attention to themselves for using a device in an unapproved manner.”); Sage, *supra* note 46, at 1022 (“Fear of malpractice liability discourages reporting.”).

76. See Barry Meier, *Flawed Device Places F.D.A. Under Scrutiny*, N.Y. TIMES, Dec. 15, 2004, at A1 (noting that “[t]he growing use of [defibrillators] in settings like offices, schools and homes puts them outside the [FDA]’s problem-reporting system”).



Overreporting is an issue as well: The MedWatch system generates some 22,000 reports each year,<sup>77</sup> and of these a substantial number may not involve a causal link between the product and the injury. The quality of the reports can limit their usefulness: "Much of the data FDA receives do not allow a complete understanding of the problems associated with an adverse event or allow the Agency to be proactive in protecting the public."<sup>78</sup>

More generally, the FDA's reporting programs generate a deluge of information. Annually, the agency has received more than 200,000 adverse event reports regarding drugs or biologic products, and more than 80,000 adverse event reports concerning devices.<sup>79</sup> It is thus unsurprising that the agency describes its analysis of this flood of data as "triage,"<sup>80</sup> and that the agency laments the difficulty of its task: "Like the proverbial search for a needle in a haystack, the number and variety of products and the lack of reliable usage information, make it difficult to distinguish variability and *noise* from a real concern. . . . More work in this area is needed."<sup>81</sup> But though more work is needed, the resources

---

77. See Michelle Meadows, *MedWatch: Managing Risks at the FDA*, FDA CONSUMER MAG., Sept.-Oct. 2003, [http://www.fda.gov/fdac/features/2003/503\\_risk.html](http://www.fda.gov/fdac/features/2003/503_risk.html).

78. RISK MANAGEMENT REPORT, *supra* note 23, at 63-64.

79. See *id.* at 54 ("In FY 1998, more than 230,000 reports of suspected adverse events were received by [the Adverse Event Reporting System]."); *id.* at 58 ("The Agency receives approximately 80,000 to 85,000 device-related adverse event reports every year."). The numbers appear to be increasing. See David W. Feigal, et al., *Ensuring Safe and Effective Medical Devices*, 348 NEW ENG. J. MED. 191, 191 (2003) ("The FDA received more than 120,000 [device-related] reports in 2002.").

80. RISK MANAGEMENT REPORT, *supra* note 23, at 58 ("When received, [medical device] reports are first triaged by medical professionals."). The agency's "triage" efforts include some measures designed to make the flow of information more manageable by cutting its volume. The FDA permits "summary reporting" of events concerning some medical devices with "well-documented adverse event histories." *Id.* at 58-59. Statutory changes in 1997, see Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 360i(b)(5) (2000), "direct[] the FDA to move away from universal, mandatory adverse event reporting by user facilities to a system based on reporting by a representative sample of facilities," RISK MANAGEMENT REPORT, *supra* note 23, at 53. In addition, the FDA is improving its electronic data systems and is seeking ways to use technology to look for emerging safety issues. See *id.* at 3 (noting that the "FDA has initiated several changes in the adverse event reporting system, such as consolidating reporting system components and using electronic reporting"); see also *FDA To Use Data Mining To Monitor Adverse Events*, 22 BIOTECHNOLOGY L. REP. 481, 481 (2003) (reporting that the FDA "has signed a Cooperative Research and Development Agreement . . . with Lincoln Technologies, Inc. . . . to use safety data as an early indicator of populations at particular risk of adverse effects and of drug interactions," and stating that "[t]he data mining will be applied to information the FDA collects from postmarket reports").

81. RISK MANAGEMENT REPORT, *supra* note 23, at 67-68.

necessary to perform the task are sorely lacking.<sup>82</sup> Observers assert that the FDA's funding arrangements have led it to privilege new drug approval while starving the CDER's postmarketing surveillance arm.<sup>83</sup>

Other critics suggest that the FDA suffers not only from a lack of resources but also from a lack of will to pursue safety issues aggressively. David Graham, the Associate Director for Science and Medicine in the FDA's Office of Drug Safety, has charged that the CDER resists airing safety concerns about approved drugs, both because the officials who approved the drug wish not to be proven wrong and because upper-level managers in the Office of Drug Safety tend to support the positions taken by those officials.<sup>84</sup>

In summary, though the FDA has made efforts to improve its postmarketing surveillance,<sup>85</sup> more should be done. The problem of insufficient resources

82. See Green, *supra* note 46, at 499 ("If the FDA had adequate resources to monitor manufacturer post-approval reporting behavior, detect violations, impose adequate sanctions, and thereby provide an appropriate deterrent, we could be more sanguine about the efficacy of the [adverse reaction reporting] process. But, once again, there is the problem of inadequate regulatory resources.").

83. See Gardiner Harris, *At F.D.A., Strong Drug Ties and Less Monitoring*, N.Y. TIMES, Dec. 6, 2004, at A2 (noting that the FDA no longer has the resources to fund independent studies of emerging safety issues and that "[i]n the past 11 years, spending on [new drug] reviews has increased to more than four-fifths of the agency's drug center budget from about half"). Citing figures from 1997, Barbara Noah has observed that "the FDA only devotes the equivalent of fifty-five full-time employees to post-approval surveillance, as compared with over 1700 full-time equivalents engaged in pre-market review of new drug applications." Noah, *supra* note 66, at 452.

84. See *Merck and Vioxx: Putting Safety First?: Hearing Before the House Comm. on Finance*, 108th Cong. (2004) [hereinafter *Vioxx Hearings*] (statement of David J. Graham, Assoc. Dir. for Sci., Office of Drug Safety, FDA).

85. Efforts continue to be made to strengthen the FDA's postmarketing oversight. For example, the FDA can premise its approval of a product on the company's commitment to perform postmarketing studies. Concerns were raised in the mid-1990s about the FDA's capacity to supervise such studies. REPORT TO CONGRESS: REPORTS ON POSTMARKETING STUDIES [FDAMA 130] 5-6 (2001), <http://www.fda.gov/cber/fdama/pstmrktfdama130.pdf>. In response, Congress in 1997 expanded the FDA's authority to follow up on drug and biologic postmarketing studies. See 21 U.S.C. § 356b (2000); Griffin et al., *supra* note 68, at 492. Some have suggested that those studies have not yet fulfilled their potential, see *id.* at 492 ("As of February 2002, only 37% of the 2400 postmarketing commitments for new drugs had been completed and many had never been started. Despite changes in FDA procedures, potential concerns or 'signals' generated before licensing can still remain unexplored for years after marketing."), and an FDA official recently remarked that the FDA "ha[s] very little authority to make sure those postmarketing commitments are carried out," Denise Grady, *A Medical Journal Calls for a New Watchdog on Drugs*, N.Y. TIMES, Nov. 23, 2004, at A1 (quoting Sandra Kweder, Deputy Director of the FDA's Office of New Drugs). But cf. FDA Report on the Performance of Drug and Biologics Firms in Conducting



persists, as does the concern that the FDA may be loath to move swiftly to address emerging safety issues.<sup>86</sup> Commentators have suggested a number of measures that might help: For example, Congress could create a new regulatory body—independent of the FDA’s medical product approval arm—that would be devoted to postmarketing surveillance.<sup>87</sup> The Institute of Medicine, which has been asked to review the FDA’s postmarketing surveillance system,<sup>88</sup> may suggest other measures. But even if changes are made, it is likely that litigation will continue to play an important role in identifying and substantiating problems. In the next Part, I consider whether the litigation and regulatory processes might be restructured so as to improve the FDA’s postmarketing surveillance.

---

Postmarketing Commitment Studies; Availability, 69 Fed. Reg. 12,162, 12,163 & tbl.1 (Mar. 15, 2004) (asserting that though 1338 drug postmarketing commitments remain open, and studies have not yet begun with respect to 864 of those commitments, only twenty-one are “delayed” in the sense that “[t]he study is behind the original schedule”).

86. As a group of doctors recently noted with respect to device regulation, “[w]hereas large resources have been devoted to . . . early development and clinical evaluation . . . , few resources have been focused on post-market surveillance . . . .” Mehran et al., *supra* note 75, at 3073.

87. See *Vioxx Hearings*, *supra* note 84 (statement of Bruce M. Psaty, M.D., Ph.D., Professor, Medicine, Epidemiology & Health Servs.); see also Editorial, *Looking for Adverse Drug Effects*, N.Y. TIMES, Nov. 27, 2004, at A14 (“Critics have proposed a wide range of reforms—a more active search for adverse consequences, increasing the power of the safety office within the F.D.A., ending the agency’s reliance on user fees from the industry and establishing a wholly independent drug safety board . . . .”). Requiring advance registration of all drug trials would reduce a company’s ability to suppress adverse information through confidentiality agreements with researchers. See Barry Meier, *Contracts Keep Drug Research Out of Reach*, N.Y. TIMES, Nov. 29, 2004, at A1. There have been many additional proposals. See, e.g., RISK MANAGEMENT REPORT, *supra* note 23, at 14-15 (listing options); U.S. GEN. ACCOUNTING OFFICE, ADVERSE DRUG EVENTS: THE MAGNITUDE OF HEALTH RISK IS UNCERTAIN BECAUSE OF LIMITED INCIDENCE DATA 18 (2000) (noting proposal to “establish[] a network of health care facilities to serve as ‘sentinel sites’ for closely monitoring the experiences of the first patients to take a new drug”); Brewer & Colditz, *supra* note 50, at 827-28 (suggesting that measures such as meta-analysis of existing studies, and analysis of information in large databases, may help to identify problem drugs); Mehran et al., *supra* note 75, at 3076 (suggesting that claims databases and device registries may provide safety information); Sage, *supra* note 46, at 992 (proposing that knowledge of drug risks “can be improved by (1) medical structures such as HMOs, which can gather information about delayed or low probability adverse drug reactions, and (2) intelligently selected legal rules governing physician competence and manufacturers’ profit incentives”).

88. See Harris, *supra* note 83.

## II. LINKING THE REGULATORY AND LITIGATION SYSTEMS

In theory, the regulatory and litigation systems could operate entirely independently: Compliance with regulations would be irrelevant in litigation, and litigation outcomes would not directly affect agency regulation.<sup>89</sup> Few, however, would advocate total independence. It seems clear that the FDA's expert assessments of product safety should not be irrelevant in litigation arising from alleged safety defects. Rather, the dispute is over what the *effects* of the FDA safety determinations should be.

As noted above,<sup>90</sup> some argue that the FDA's expert balancing of product risks and benefits leaves no room for disagreement within the tort system. In this view, there is no reason for judges or juries to second-guess the FDA's judgments, and, indeed, second-guessing is likely to produce undesirable results because of the limited capabilities and circumscribed perspective of a civil jury.

Others, however, point out that the FDA cannot discern and address all product safety issues ahead of time, and that the agency may not act quickly enough to address those issues when they arise after a product enters the market. Even if agency capture does not inhibit the FDA's investigation of a safety problem, other limits on the FDA's postmarketing surveillance capacity may produce a similar effect. Scholars have also noted a substantial body of data that suggests juries do better at assessing technical and scientific questions than their critics assert.<sup>91</sup>

Courts considering the effects of FDA determinations have struggled to balance these competing considerations and have developed a number of doctrinal methods for doing so. FDA determinations can help a plaintiff establish a claim, but they may also help a defendant avoid liability. And in recent years, some—including, recently, the FDA itself—have asserted that certain types of FDA determinations ought to preclude litigation altogether.

Though there is no private right of action for violation of requirements imposed under the Food, Drug, and Cosmetic Act (FDCA),<sup>92</sup> such a violation is hardly irrelevant in cases asserting products liability under state law. A violation of FDA-imposed requirements can be the basis for a finding of negligence *per*

---

89. Obviously, litigation itself has regulatory effects. *See, e.g.,* W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1448 (1994) ("The common law regulates behavior through the imposition of damage awards against tortfeasors."). My point here, however, is to consider the extent to which litigation outcomes might operate independently from agency decisions.

90. *See supra* text accompanying notes 3-4.

91. *See supra* note 9.

92. 21 U.S.C. §§ 301-399 (2000); *see Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) ("[N]o private right of action exists for a violation of the FDCA.").

*se*.<sup>93</sup> Even if the violation does not establish negligence *per se*, it can be considered to be evidence of negligence.<sup>94</sup>

Conversely, some have argued that compliance with FDA requirements should establish a defense to negligence claims.<sup>95</sup> Under a regulatory compliance defense, “[m]anufacturers of drugs and extensively regulated devices would be shielded from liability by compliance with FDA regulations, including conformance with agreed-upon testing protocols and timely submission and complete, accurate description of all required information.”<sup>96</sup> Proponents assert that this system “would strengthen current incentives to comply with FDA regulations, while attenuating current incentives to exceed FDA safety standards.”<sup>97</sup> Acting upon such principles, some states have barred punitive damages where a defendant has met FDA requirements.<sup>98</sup>

Similarly, some states have essentially rejected the notion that an FDA-approved drug can suffer from a design defect. An influential comment in the Restatement (Second) of Torts set the terms of the debate by asserting that many drugs are “unavoidably unsafe” and that the manufacturers of such products should not incur liability in the absence of manufacturing defects or inadequate warnings.<sup>99</sup> Most jurisdictions purport to follow this rule, but they disagree on its

93. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 note (1998) (“The overwhelming majority of American courts hold that violations of product safety regulations cause products to be defective as a matter of law in cases involving both design and failure to warn.”); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 965 (E.D. Wis. 1981) (holding that a violation of FDA requirements concerning contraceptive labeling would establish negligence *per se* under Wisconsin law), *amended by* 532 F. Supp. 211 (E.D. Wis. 1981). *But see, e.g., King v. Danek Med. Inc.*, 37 S.W.3d 429, 460 (Tenn. Ct. App. 2000) (rejecting negligence *per se* claim that was based on defendant’s failure to obtain premarket approval or clearance for medical device).

94. See, e.g., *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 71 (Mass. 1985) (stating in dictum that “violation of FDA requirements is evidence, but not conclusive evidence, of negligence”).

95. See, e.g., Viscusi et al., *supra* note 89, at 1478-80 (arguing that in the absence of fraud, compliance with FDA requirements should preclude tort liability).

96. STEVEN GARBER, *PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES*, at xxxii (1993). The defense could take several different forms. For example, compliance could provide a rebuttable presumption that liability should not attach. See, e.g., N.J. STAT. ANN. § 2A:58C-4 (West 2005) (“If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the [FDA] . . . a rebuttable presumption shall arise that the warning or instruction is adequate.”).

97. GARBER, *supra* note 96, at xxxii.

98. See Viscusi et al., *supra* note 89, at 1476 n.140 (citing statutes).

99. As the comment explained:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially

scope. Many courts engage in a case-by-case risk/benefit analysis to determine whether a particular drug or device is “unavoidably unsafe.”<sup>100</sup> Some other courts, however, have concluded that all prescription drugs should be viewed as “unavoidably unsafe,” such that the manufacturer should not be liable on a design defect theory.<sup>101</sup> Though a blanket application of the rule seems less persuasive with regard to medical devices than with regard to pharmaceuticals,<sup>102</sup> some courts have found whole categories of medical devices to be “unavoidably unsafe” as well.<sup>103</sup> A strong undercurrent in the case law broadly applying the

---

common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k (1965). The *Restatement (Third) of Torts: Products Liability* proposes a different test:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6(c) (1997). This standard has been criticized by both courts, *see, e.g.*, *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 839-40 (Neb. 2000) (reviewing objections to Section 6(c) and rejecting it because “recovery [under this standard] would be nearly impossible”), and commentators, *see, e.g.*, George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1089 (2000) (arguing that Section 6(c)’s “declaration that manufacturers of medical products need not make a safer product if the existing product does more good than harm reverses thirty-five years of safety-advancing products-liability law”). *But see* James A. Henderson & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2001) (responding to Conk’s critique).

100. *See, e.g.*, *Freeman*, 618 N.W.2d at 840 (holding in a prescription drug case that comment k will provide an affirmative defense “when it is shown that (1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe”); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (applying similar test in medical device case).

101. *See, e.g.*, *Grundberg v. Upjohn Co.*, 813 P.2d 89, 99 (Utah 1991).

102. Alternative designs of prescription drugs may often be impossible to find or create. *But see* 5 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, *PRODUCTS LIABILITY* § 50.03A[3], at 50-29 (2004) (noting that birth control pills “can be designed in many different ways”). However, it seems likely that alternative designs of many medical devices could be pursued. *See* GARBER, *supra* note 96, at xxviii (noting that medical devices “can often be made safer at low or moderate costs”). Take for example the variety of possible designs for intrauterine devices (IUDs). *See* RONALD J. BACIGAL, *THE LIMITS OF LITIGATION: THE DALKON SHIELD CONTROVERSY* 10 (1990) (describing the choice between monofilament and multifilament tail strings for IUDs and explaining that the Dalkon Shield’s multifilament tail strings “wicked” bacteria into the uterus).

103. *See, e.g.*, *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 384 (Cal. Ct. App. 1992) (holding that “all implanted medical devices” should be viewed as unavoidably unsafe). *But see* GARBER, *supra*



“unavoidably unsafe” notion is that the FDA’s approval of a medical product evidences an authoritative judgment that the product’s benefits outweigh its risks.<sup>104</sup>

Even in the absence of structural connections between the litigation and regulatory systems, then, strong substantive connections exist. Violation of FDA requirements can help establish liability, while compliance can sometimes help defend against a claim or mitigate its damages. Some advocates of “tort reform,” however, contend that the regulatory-adjudicative relationship must be structured more formally through the mechanism of preemption. Under the current system, when FDA regulation preempts state tort claims, the regulatory system displaces the litigation system. Because no federal cause of action currently exists, preempting state tort claims eliminates the potential for lawsuits concerning product safety.

Questions of preemption currently turn upon both the nature of the claim and the degree of prior FDA scrutiny of the product. Claims seeking damages from a company that violated FDA requirements are not preempted.<sup>105</sup> Nor are claims challenging the safety of a medical device approved under the relatively streamlined “substantial equivalence” process.<sup>106</sup> Claims asserting that the defendant perpetrated a fraud on the FDA, however, are preempted.<sup>107</sup> And while there is a circuit split on the question of preemption for claims with respect to medical devices that have survived the more rigorous “premarket approval” process, the emerging majority view is that such claims are impermissible.<sup>108</sup> In

---

note 96, at 39 (“It is unclear whether comment k has been as widely applied to devices as to drugs and biologicals.”).

104. For example, the *Grundberg* court explained its holding as follows:

In light of the strong public interest in the availability and affordability of prescription medications, the extensive regulatory system of the FDA, and the avenues of recovery still available to plaintiffs by claiming inadequate warning, mismanufacture, improper marketing, or misrepresenting information to the FDA, we conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah.

*Grundberg*, 813 P.2d at 99.

105. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (holding that “[n]othing . . . denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements”).

106. See *id.* at 494.

107. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that “state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law”). But see McGarity, *supra* note 44, at 572 (arguing that *Buckman*’s holding should be narrowly construed).

108. Compare *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (finding preemption where

the area of prescription drugs, although most lower courts have rejected the preemption defense in failure-to-warn cases, at least one has disagreed.<sup>109</sup>

The FDA, in its notorious 2002-2004 court filings, took up the defendants' side of the argument in both of the latter disputes.<sup>110</sup> Moreover, there are indications that the Bush Administration intends to expand the reach of preemption in other ways. A bill introduced in the Senate during the 108th Congress would have immunized manufacturers from punitive damages in connection with medical products unless the plaintiff shows by clear and convincing evidence that the manufacturer violated a specific requirement imposed under the FDCA.<sup>111</sup> Despite recent events concerning Vioxx and other controversial FDA-approved drugs, it appears likely that the Administration will continue to press for passage of this measure.<sup>112</sup> Thus, it continues to be important to assess the arguments of those who support preemption of claims for medical products liability.

As can be seen from this summary, each proposal to take tort claims away from civil juries rests upon the assertion that jury determinations of product safety are at best duplicative—because the FDA exists to make just such safety assessments—and at worst harmful because unwarranted jury awards can deter companies from developing and marketing useful products. But, as I have noted, those positions have been subjected to powerful critiques. In addition to

medical device went through premarket approval process); *Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (same); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227 (6th Cir. 2000) (same); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (same); *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997) (same), *with* *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (finding no preemption).

109. *Compare* *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000) (rejecting preemption defense in prescription drug failure-to-warn case and noting that “most courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims”), *with* *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (holding failure-to-warn claim preempted because “[t]he FDA dictates the contents of the label for Adderall® and defendants were prohibited from changing it without prior approval from the FDA, except in limited circumstances for a limited period of time”), *aff’d on other grounds*, 367 F.3d 1013 (8th Cir. 2004).

110. *See, e.g., Horn*, 376 F.3d at 177-79 (describing FDA’s arguments in support of preemption, based on FDA premarket approval, in a medical device case); Brief of Amicus Curiae United States at 2, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2002) (No. 02-55372) (advocating preemption, in a prescription drug case, because “[t]o require a warning of a supposed danger that FDA concludes has no actual scientific basis, no matter the warning’s language, would be to require a statement that would be false or misleading, and thus contrary to federal law”).

111. Patients First Act of 2003, S. 11, 108th Cong. § 7(c)(1).

112. *See* Bob Herbert, *A Gift for Drug Makers*, N.Y. TIMES, Jan. 14, 2005, at A23 (criticizing the Administration’s position).



challenging the notion of jury incompetence, commentators have argued persuasively that some amount of redundancy is desirable: The tort system should remain free to redetermine product safety in the light of information developed during litigation, because the FDA may not always uncover relevant safety information and may not act quickly enough upon the information that it does receive.

Proposals for FDA regulation to displace tort litigation—either through preemption or through a regulatory compliance defense—cannot fully meet this objection. A carefully designed regulatory compliance defense might attempt to improve postmarketing surveillance, for instance by precluding liability if and only if the defendant had complied with regulatory requirements, including disclosure requirements.<sup>113</sup> Thus, proponents have urged that the defense should be available only where there was full disclosure.<sup>114</sup> But even with this caveat, the effectiveness of such a system would require that the FDA act quickly and effectively to address all indications of emerging safety problems. Especially in the light of recent questions concerning the FDA's performance, this assumption seems unduly optimistic. A regulatory compliance defense would remove a company's incentive to work proactively to address emerging safety issues; to avoid liability, the company would simply have to disclose any relevant information to the FDA.<sup>115</sup> And such disclosures might well not facilitate the FDA's task: A system in which disclosure provided immunity would encourage companies to inundate the FDA with information.

So long as the regulatory and litigation systems remain structurally separate, the policy debate may have reached an impasse: In order to privilege FDA

---

113. Michael Green has pointed out that incorporating such nuances into the regulatory compliance defense will render that defense complex and costly to litigate. *See* Green, *supra* note 46, at 507-08.

114. *See* 2 AM. LAW INST., REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 97 (1991) [hereinafter ALI REPORTERS' STUDY] (arguing that a regulatory compliance defense should apply only if the defendant "publicly disclosed to the relevant regulatory agency any material information . . . of which it has reason to be aware . . . concerning the risks posed by the defendant's activities and/or the means of controlling them," and stating that the requirement should "extend to information indicating that agency standards or tests may be inadequate or inappropriate").

115. As Michael Green has noted:

With a regulatory compliance defense available, manufacturers would no longer have an incentive to seek labeling changes that would disclose additional risks discovered in the post-marketing period. The impetus for such changes would be left to the FDA . . . . The specter of inadequate resources available to the FDA makes this role reversal of significant concern.

Green, *supra* note 46, at 502.

decisionmaking, one must lose the added benefits that the tort system could provide. In particular, eliminating litigation would deprive regulators of a potentially useful source of information on product safety<sup>116</sup> and would repose in the FDA and the regulated companies a level of trust that seems unwarranted in the light of recent events. In this Part, I explore some structural options that could offer a way around the dilemma. Each of the options I consider would preserve some opportunity for persons injured by medical products to obtain compensation, and some of those options would also preserve a role for the private plaintiffs' bar in bringing safety problems to light. As I will argue, a system that preserves those compensatory and monitoring functions is preferable to preemption, which would sacrifice both.

I will compare four ways in which Congress could link litigation to regulation. In each option described here, Congress would preempt state tort claims and substitute a federal cause of action. On the assumption that one goal would be to submit safety and causation questions to the FDA (or other expert agency) for resolution, each of the options described here would incorporate agency determinations of liability. A basic question in that regard is whether, in light of the fact that key liability questions would be determined by the FDA, the rest of the proceeding should unfold within an agency setting, or whether the suit should be litigated in federal court with a mechanism for referring specific questions to the FDA. I first consider two options for situating the adjudication within the agency itself; I then outline two possible frameworks for litigation in federal court. Finally, I compare the four options in the light of a number of constitutional and policy considerations.

Before embarking on this comparison, I should note that my discussion assumes that the tort system should seek to apply the same substantive standard, and roughly the same evidentiary requirements, that the FDA employs in making its safety determinations. This assumption is, of course, debatable; it is not uniformly reflected in current state tort law, and it need not guide the choice of substantive and evidentiary standards under a new federal cause of action either. However, much of the debate over the interaction between FDA regulation and tort liability presumes that the standards should be the same and focuses on asserted flaws in one or the other institution's application of those standards. My project is not to defend a particular choice of substantive liability rules, but rather to examine whether structural changes could improve the application of the chosen standard. On that premise, I will proceed to consider possible alternatives.

---

116. *Cf. id.* at 482 ("Sometimes it is the tort system that uncovers instances of noncompliance with FDA regulatory standards, rather than the FDA itself.").

### A. Agency Adjudication

One possible approach would be to situate the adjudication of product safety claims within the agency itself. Such adjudication could proceed on the government's initiative; in addition, Congress could authorize private persons to bring claims.

#### 1. Agency Enforcement

In an agency enforcement model, Congress would preempt private state tort claims and replace them with a claim by the government for penalties. The germ of such a penalty system already exists within the framework of the FDCA.

Though the FDA's principal enforcement options include injunctions, civil seizures, and criminal penalties,<sup>117</sup> it also has authority to seek civil penalties<sup>118</sup> for violations of certain laws governing prescription drugs<sup>119</sup> and medical devices.<sup>120</sup> Civil penalty proceedings begin with a complaint by the relevant center within the FDA.<sup>121</sup> The respondent can request a hearing, at which it can be represented by counsel.<sup>122</sup> The presiding officer at the hearing has the power to subpoena witnesses and evidence.<sup>123</sup> Discovery is more circumscribed than in civil court proceedings: Though parties can obtain discovery of documents if they establish that the documents are "relevant to the issues before the presiding officer,"<sup>124</sup> to obtain permission to take depositions, they must show that the

117. See Megan Hanley Baer & Whitney Moore, *Federal Food and Drug Act Violations*, 40 AM. CRIM. L. REV. 613, 631-33 (2003) (discussing criminal penalties for violations of the FDCA).

118. In addition, at least one court has held that the FDA can bring a claim for restitution arising from violations of the FDCA. See *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 762 (6th Cir. 1999) (holding that "nothing in the FDCA precludes a court sitting in equity from ordering restitution in appropriate cases"). This view, however, is not universally shared. See *id.* at 761 (noting "a number of district court cases that determine that recalls and disgorgement are unavailable under the FDCA"); see also Jeffrey N. Gibbs & John R. Fleder, *Can FDA Seek Restitution or Disgorgement?*, 58 FOOD & DRUG L.J. 129, 147 (2003) (criticizing *Universal Management Services*).

119. See 21 U.S.C. § 333(b)(2)-(3) (2000).

120. See *id.* § 333(f)(1)(A).

121. See 21 C.F.R. § 17.5 (2004).

122. See *id.* §§ 17.9, 17.15.

123. See *id.* §§ 17.19, 17.27.

124. *Id.* § 17.23. This standard may roughly correspond to the current presumptive standard in federal civil practice. See FED. R. CIV. P. 26(b)(1) (setting general rule that "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party"). However, in federal litigation a party may be able to obtain a court order authorizing broader discovery. See *id.* (providing that "[f]or good cause, the court may order discovery of any

information sought is not available in some other way and that “relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.”<sup>125</sup> Direct testimony at the hearing is given in writing, but cross-examination occurs through live testimony.<sup>126</sup> The evidentiary rules are more relaxed than those applied in federal court, though the hearing officer may draw upon the Federal Rules of Evidence for guidance.<sup>127</sup> Liability and size of penalty must be proven by a preponderance of the evidence.<sup>128</sup> Either side may appeal the hearing officer’s decision within the FDA; findings of fact are reviewed for “substantial evidence” and conclusions of law are reviewed *de novo*.<sup>129</sup> A dissatisfied respondent may then seek judicial review of the final agency decision.<sup>130</sup>

Though the current system provides a starting point for an agency enforcement model, it would require some adjustment. Penalties available under current law are directed toward deterrence but not compensation. Neither the maximum allowable penalties<sup>131</sup> nor the factors to be considered<sup>132</sup> relate to the extent of harm caused by a violation. The money recovered goes into the general treasury,<sup>133</sup> not toward compensation of injured persons. If an agency enforcement proceeding were to substitute for private civil actions, the amount of the penalties could be keyed to the level of damages incurred by consumers, and the proceeds could be earmarked for distribution to injured persons. The other

---

matter relevant to the subject matter involved in the action”).

125. 21 C.F.R. § 17.23 (2004).

126. *See id.* § 17.37.

127. *See id.* § 17.39.

128. *See id.* § 17.33. The decisionmaker must consider aggravating and mitigating circumstances and articulate the reasons for the chosen penalty. *See id.* § 17.34.

129. *See id.* § 17.47.

130. *See id.* § 17.51. Because the FDA’s penalty procedure includes a public hearing, *see id.* § 17.33(d) (“The hearing shall be open to the public unless otherwise ordered by the presiding officer . . .”), and results in the development of an administrative record, it appears likely that the FDA’s decision would be reviewed in federal court using the “substantial evidence” standard set forth in 5 U.S.C. § 706(2)(E) (2000). *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971) (“Review under the substantial-evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself . . . or when the agency action is based on a public adjudicatory hearing.”).

131. *See* 21 U.S.C. § 333(b)(2)-(3), (f)(1)(A) (2000) (setting maximum penalties); 21 C.F.R. § 17.2 (2004) (adjusting maximum penalties for inflation).

132. *See, e.g.,* 21 U.S.C. § 333(f)(3)(B) (2000) (with respect to penalties for medical device violations, factors include “the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, [and] the degree of culpability”).

133. *See* 21 C.F.R. § 17.54 (2004).

major change would be that the agency's enforcement resources would have to be increased, as would its staffing for internal hearings.

## 2. *Private Enforcement*

Alternatively, Congress could preempt state tort claims, and substitute a system of private products liability claims that would be adjudicated within the agency. That adjudication could employ procedures similar to those discussed in Subsection II.A.1. above. Some differences, however, would arise from the presence of private plaintiffs in the suit. For example, it would be necessary to provide procedures to govern the joinder of multiple plaintiffs, either as named parties or as members of a plaintiff class. In non-class actions where liability was proven, damages would be determined on an individual basis; in class actions, a finding of liability might be followed by a determination of aggregate damages and the adoption of a set of guidelines for distributing those damages to class members. Although a private enforcement system of this type would remove the need for additional government enforcement resources, it would still entail a substantial increase in the number of agency personnel staffing the hearing process.

## B. *Hybrid Adjudication*

Thus far, the discussion has assumed that the desirability of obtaining FDA resolution of safety and causation issues would dictate that the litigation should occur within the administrative system. An alternative, however, would be to permit claims to proceed in federal court, but refer certain issues to the FDA for resolution.<sup>134</sup> In a 1996 article, Richard Nagareda made a similar proposal for the treatment of mass torts.<sup>135</sup> He suggested that Congress enact a scheme under which the doctrine of "primary jurisdiction" would come into play when a particular mass tort resulted in federal litigation that merited consolidation by the

---

134. Existing rules provide somewhat analogous mechanisms. A court can refer a matter to the FDA for administrative determination, and if the Commissioner accepts the referral, the FDA can employ a range of procedures to determine the referred matter. *See* 21 C.F.R. § 10.60 (2004). Thus, for example, courts have referred to the FDA the question of whether a product falls within the definition of a "new drug" under 21 U.S.C. § 321(p) (2000). *See Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653 (1973) ("[T]he District Court's referral of the 'new drug' and the 'grandfather' issues to FDA was appropriate, as these are the kinds of issues peculiarly suited to initial determination by the FDA.").

135. *See Nagareda, supra* note 15, at 353; *see also id.* at 359 (stating that "the FDA would seem to be a strong candidate for" inclusion in his proposal).



Panel on Multidistrict Litigation.<sup>136</sup>

The primary jurisdiction doctrine requires a court to stay (or dismiss) an action so as to defer to agency determination of an issue (or a claim) in appropriate cases.<sup>137</sup> The rationales for deference to the agency may include a need for uniform agency determination of an issue,<sup>138</sup> as well as a recognition of superior agency expertise, particularly with respect to specialized facts within the agency's field of experience.<sup>139</sup> Primary jurisdiction has loomed large in certain areas of federal regulation; for example, the doctrine has played a prominent role in coordinating the reach of federal antitrust lawsuits with the authority of other federal regulatory schemes. The doctrine has not, however, yet been employed as a way to link the mass tort and regulatory systems. Nagareda proposed that the doctrine could be used as a way, in effect, to refer to an agency (such as the FDA) a question (such as general causation) that would benefit from the agency's decisionmaking.<sup>140</sup> The proposal I describe here is similar to Nagareda's in that it contemplates that litigation would be commenced in court but that the court would (at an appropriate juncture) refer issues of product safety and causation to the FDA for determination.

Discovery, in this system, would be supervised by the federal court. After discovery, the defendant could obtain summary judgment<sup>141</sup> unless the plaintiff

136. *See id.* at 361 ("The primary jurisdiction doctrine would apply only if [the] litigation . . . progresses to the point that similar claims inundate the federal system, so many as to warrant consolidation by the MDL Panel and to trigger the opportunity to petition the relevant regulatory agency.").

137. *See, e.g., Reiter v. Cooper*, 507 U.S. 258, 268 (1993) (stating that where a claim "contain[s] some issue within the special competence of an administrative agency," the doctrine of primary jurisdiction "requires the court to enable a 'referral' to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling").

138. *See, e.g., Tex. & Pac. Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 440-41 (1907) (stressing need for uniform determinations concerning railroad rates). *But see Great N. Ry. v. Merchs. Elevator Co.*, 259 U.S. 285, 290-91, 294 (1922) (holding that prior resort to agency is not necessary in order to obtain uniform determination of a pure question of law, because review by the Supreme Court can ensure uniformity with respect to such questions).

139. *See, e.g., Far E. Conference v. United States*, 342 U.S. 570, 574-75 (1952) ("Uniformity and consistency in the regulation of business entrusted to a particular agency are secured . . . by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.").

140. *See Nagareda, supra* note 15, at 361.

141. As in current federal civil litigation, a defendant moving for summary judgment would "bear[] the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine



pointed either to evidence that the defendant violated FDA requirements or to new information concerning product harmfulness. To survive summary judgment on the latter ground, the plaintiff would have to show the existence of information, material to the product's safety, that the FDA did not consider when it initially approved the product. That showing, or a showing of facts from which a reasonable decisionmaker could infer that the defendant violated FDA requirements, would entitle the plaintiff to a bench trial.<sup>142</sup>

The trial would be segmented, because the court would refer questions of product safety and causation to the FDA.<sup>143</sup> The FDA would initially submit the questions to an advisory committee for nonbinding determination. The advisory committee could resemble those currently employed by the FDA to assist it with new product reviews and other matters.<sup>144</sup> Advisory committees can enhance the accuracy of the FDA's decisionmaking and improve its credibility; they can also

---

issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

142. Procedure under the proposed system would differ from ordinary summary judgment procedure for two reasons: first, because the system does not contemplate a jury trial, and second, because the system divides liability questions between the district judge and the FDA.

As to questions relegated to the district judge, a summary judgment motion might sometimes provide an occasion for the judge to resolve the questions without taking live testimony:

When evidentiary issues are in dispute, when the credibility of witnesses may be in issue, when conflicting evidence must be weighed, a full trial is clearly necessary regardless of whether it is a bench or jury trial . . . . But when the question for decision concerns drawing inferences from undisputed evidence, or interpreting and evaluating evidence to derive legal conclusions, a trial may not add to the judge's ability to decide.

WILLIAM W. SCHWARZER ET AL., *THE ANALYSIS AND DECISION OF SUMMARY JUDGMENT MOTIONS* 39 (1991).

By contrast, as to questions entrusted to the FDA, it might be appropriate for the judge to play even less of a role in screening cases through summary judgment than the judge would ordinarily play in a case where the right to a jury is asserted. In the context of jury trials, the judge plays the role of gatekeeper by determining the admissibility of expert testimony. Judges may be well suited, in comparison to juries, to serve such a function. However, as to questions that the proposed system would relegate to the FDA, little purpose would be served by requiring the judge rigorously to screen expert evidence for admissibility prior to sending the issues to the FDA: The advisory committee and agency officials are better equipped to assess such evidence.

143. Some safety and causation issues might be suitable for determination by the district court (assisted where necessary by a special master). For example, safety determinations could be straightforward in cases involving violations of existing FDA requirements. Also, one of the causation issues in failure-to-warn cases is whether the physician would have prescribed the product even if the appropriate warning had been given; that issue might not require resolution by the FDA. *See infra* note 332.

144. Such committees are governed by the Federal Advisory Committee Act, 5 U.S.C. app. 2 §§ 1-16 (2000), as well as by FDA regulations, *see* 21 C.F.R. §§ 14.1-.174 (2004).

provide an opportunity for stakeholder and public input concerning important decisions. Employing an advisory panel to assist the FDA in liability determinations could carry similar benefits.

Panel members would be selected through a public nomination process,<sup>145</sup> and would include researchers with relevant scientific and medical expertise. FDA committees can also include members selected to represent consumer, patient, and industry interests. The liability panel could include such stakeholder representatives, but it would be necessary to screen carefully for conflicts of interest and to protect against an appearance of bias. Conflicts screening would also be key as to medical experts.<sup>146</sup> Although members of FDA advisory committees are subject to federal disclosure and conflicts provisions that ban participation by those with financial interests in the outcome,<sup>147</sup> the conflict can be waived if “the official responsible for the employee’s appointment . . . certifies in writing that the need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest involved.”<sup>148</sup> Critics charge that conflicts are routinely waived, even in instances where waiver is unwarranted.<sup>149</sup> Because the proposed system would place significant reliance

145. Cf. 21 C.F.R. § 14.82 (2004) (providing nomination process for voting members of standing advisory committees); *id.* § 14.84 (providing nomination process for nonvoting members of standing technical advisory committees).

146. Cf. Gardiner Harris & Alex Berenson, *10 Voters on Panel Backing Pain Pills Had Industry Ties*, N.Y. TIMES, Feb. 25, 2005, at A1 (“Ten of the 32 government drug advisers who last week endorsed continued marketing of . . . Celebrex, Bextra and Vioxx have consulted in recent years for the drugs’ makers, according to disclosures in medical journals and other public records.”). Partly as a result of the Bayh-Dole Act, which fostered ties between industry and academia, *see* ANGELL, *supra* note 47, at 8 (“The Reagan years and Bayh-Dole . . . transformed the ethos of medical schools and teaching hospitals . . . . One of the results has been a growing pro-industry bias in medical research . . .”), a large proportion of biomedical researchers derive material benefits from their relations with industry. A recent analysis found multiple studies documenting ties between researchers and industry: “Studies suggest that 23% to 28% of academic investigators in biomedical research receive research funding from industry. A 1998 survey found that 43% of investigators also receive research-related gifts . . . . Approximately one third of investigators at academic institutions have personal financial ties with industry sponsors.” Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454, 456 (2003).

147. *See* 18 U.S.C. § 208(a) (2000).

148. *Id.* § 208(b)(3); *see also* FDA, Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts, at <http://www.fda.gov/oc/advisory/conflictsofinterest/policies.html> (last visited Sept. 19, 2004).

149. *See* ANGELL, *supra* note 47, at 210 (stating that the FDA “regularly waives [the conflicts rules] on the unlikely grounds that someone’s advice is indispensable”). Angell cites a *USA Today* study that “examined FDA hearing records in 2000 and found that ‘at 92 percent of the meetings at

on the panel process, measures should be taken to ensure that conflicts are identified, and waivers should be granted only rarely and only upon a rigorous showing of necessity.

Panel meetings would presumptively be open to the public,<sup>150</sup> and they could include an opportunity for public comment.<sup>151</sup> The panel would consider evidence submitted by the parties, and could request additional information that it considered necessary. The panel's determinations would be reviewed by the FDA, which would render the final determination concerning the safety and causation questions. Regarding safety, the FDA would determine whether the product is too dangerous to remain on the market, and whether (if the product is worth keeping on the market) it should be subjected to restrictions such as additional safety warnings. The FDA could address questions of causation by listing the factors and analysis that would determine whether a particular person's injury was caused by the defect in question.

The FDA's determination would be sent to the district court. The judge would review the FDA's safety and causation findings to ensure that they were supported by some evidence and that the agency had complied with the procedural requirements described above. If warranted, the district court would then apply the FDA's causation guidance, assess damages, and enter judgment.

### *1. Private Claims*

Congress might attempt to use the hybrid system to adjudicate private claims. To accomplish this, Congress would preempt state tort claims and substitute a federal products liability claim that could be brought in federal district court. The claim would be adjudicated using the procedures described above.

Though this option has the advantage of being relatively uncomplicated, it would be vulnerable to constitutional challenge (as I explain in Subsection II.C.1.c below). Thus, it is worthwhile to consider whether a constitutionally permissible alternative exists.

---

least one member had a financial conflict of interest,' and 'at 55 percent of meetings, half or more of the FDA advisers had conflicts of interest.'" *Id.* (quoting Dennis Cauchon, *FDA Advisors Tied to Industry*, USA TODAY, Sept. 25, 2000, at A1).

150. *Cf.* Federal Advisory Committee Act, 5 U.S.C. app. 2 § 10 (2000) (setting presumption of openness); 21 C.F.R. § 14.20 (2004) (providing for public notice of advisory committee meetings); *id.* § 14.22 (providing for public access to the open portion of advisory committee meetings). Portions of the meetings could be closed as necessary. *Cf. id.* § 14.25 (providing for closed presentation of data and closed deliberations under certain circumstances).

151. *Cf. id.* § 14.29 (providing opportunity for public comment at committee meetings).

## 2. *Qui Tam* Claims

*Qui tam* claims on behalf of the government could provide another way to harness litigation as a supplement to the regulatory process. Under such a system, state tort claims would be preempted but the United States would possess a *parens patriae* claim for harms to consumers. A *qui tam* mechanism would permit such claims to be initiated and litigated by a private person, subject to federal supervision and review.<sup>152</sup> A portion of the defendant's damages payment would provide a bounty for the *qui tam* relator and the rest would fund an administrative compensation scheme for victims.

Congress can authorize the United States to sue as *parens patriae* to recover damages for injuries arising from a company's violations of federal law.<sup>153</sup> *Parens patriae* suits are an appropriate way for a government to protect the health and welfare of its citizens,<sup>154</sup> and suits concerning the safety of FDA-

---

152. Readers familiar with Jonathan Siegel's discussions of *qui tam* suits and state sovereign immunity will see that I am borrowing from him the notion of *qui tam* suits in *parens patriae*. See Jonathan R. Siegel, *Congress's Power To Authorize Suits Against States*, 68 GEO. WASH. L. REV. 44 (1999) [hereinafter Siegel, *Suits Against States*]; Jonathan R. Siegel, *The Hidden Source of Congress's Power To Abrogate State Sovereign Immunity*, 73 TEX. L. REV. 539 (1995).

The *qui tam* device came into use in English law long before the founding of the United States. See *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774-75 (2000). The first Congress under the Constitution adopted the device, and since then various American statutes have employed it; the most prominent current example is the False Claims Act. See *id.* at 768 & n.1, 776.

Some have proposed the extension of the *qui tam* mechanism to provide for enforcement of federal regulatory requirements in areas such as medical product regulation or environmental law. See, e.g., Pamela H. Bucy, *Private Justice and the Constitution*, 69 TENN. L. REV. 939, 940 (2002) (arguing that "the [False Claims Act's] private justice model should be expanded to two areas: protection of financial markets and protection of the environment"); McGarity, *supra* note 44, at 580 (suggesting that a "statute, modeled on the [False Claims Act], creating a federal private right of action for damages caused by wrongful manipulation of a licensing regime administered by a federal agency" could help to address "situations in which companies make false claims to a federal agency about the safety and efficacy of their regulated products"). However, such discussions have not proposed a hybrid adjudicatory scheme such as the one outlined here.

153. See Siegel, *Suits Against States*, *supra* note 152, at 69. As Siegel notes, "[a] statute authorizing the federal government to espouse private claims . . . may give the government the right to collect any sums that the defendant would have had to pay in a suit brought by the injured private party." *Id.* (noting as an example that the Fair Labor Standards Act "empowers the Secretary of Labor to bring suit against any employer who has violated the Act and to distribute any sums recovered to affected employees").

154. "[A] State has a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*,



regulated products clearly implicate the federal government's interest in consumer welfare.<sup>155</sup>

The *parens patriae* model is often thought to be particularly appropriate for harms that affect a substantial portion of the population. This is likely to be true of many medical products liability claims. Especially in light of the speed with which new medical products spread through the market, a safety problem with such a product is likely to create a large number of claimants. In particular, claims concerning pharmaceuticals will ordinarily involve large numbers of potential claimants, because harms to only a handful of people will not be amenable to proof. (A manufacturing defect might cause isolated injuries; but manufacturing defects are unusual in the field of pharmaceuticals, if not in the area of devices.)<sup>156</sup>

Moreover, though most *parens patriae* actions allege harm to large numbers of citizens, arguably the real touchstone should be, not the number of persons already harmed, but the degree of government interest in regulating the challenged conduct. As the Court explained with respect to a *parens patriae* action by Puerto Rico, one factor "in determining whether an alleged injury to the health and welfare of its citizens suffices to give the State standing to sue as *parens patriae* is whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers."<sup>157</sup> The FDA has a clear interest in addressing product safety problems before those problems harm large numbers of people. Allowing *parens patriae* claims of the type posited here would further that mission, even if the group of people who have so far suffered harm is a small one.

*Parens patriae* actions, then, could usefully enforce medical product safety standards and obtain damages for harm to consumers. However, the United States' litigation resources are limited, and as discussed above, the government will not always discern safety problems quickly. To address these issues,

---

458 U.S. 592, 607 (1982); see also Larry W. Yackle, *A Worthy Champion for Fourteenth Amendment Rights: The United States in Parens Patriae*, 92 NW. U. L. REV. 111, 142 (1997) (discussing *Snapp*).

155. Cf. Nagareda, *supra* note 15, at 327-28 (noting that mass torts are not "purely private disputes" and that they "more closely resemble the issues of broad public concern that constitute the daily business of the administrative state").

156. See RISK MANAGEMENT REPORT, *supra* note 23, at 8 ("Injury from product defects is unusual in the United States because of the great attention paid to product quality control and quality assurance during manufacturing.").

157. *Alfred L. Snapp & Son*, 458 U.S. at 607 (noting that "[a]lthough more must be alleged than injury to an identifiable group of individual residents, the indirect effects of the injury must be considered as well in determining whether the State has alleged injury to a sufficiently substantial segment of its population").



Congress could authorize private persons to bring the *parens patriae* suit on behalf of the United States.

This proposal is modeled loosely on the *qui tam* provisions in the False Claims Act,<sup>158</sup> although the specific features of the *qui tam* suit proposed here would be set by the statute authorizing the new system. The *qui tam* mechanism permits a private person (the “relator”) to sue to recover damages for harm to the United States; in return, a successful *qui tam* relator receives a cut of the damages recovered. The primary justifications for the use of the *qui tam* mechanism under the False Claims Act apply in the present context as well. In at least some instances, the best evidence concerning an unsafe product will be known only to company insiders; but those insiders often will not come forward without a monetary incentive.<sup>159</sup> As noted, the federal government’s limited resources prevent it from pursuing all potentially valid claims.<sup>160</sup> Moreover, in some instances an agency might fail to pursue a claim because of undue influence from the regulated industry.<sup>161</sup> Allowing private litigants to press claims on behalf of the government could address these concerns.

Congress could authorize the assertion of *qui tam* claims when a medical product had harmed consumers. An injured consumer could bring the suit; so could a person—such as a company insider—who possesses significant nonpublic information that supports the claim.<sup>162</sup> At the outset of the suit, the government would have an opportunity to review the relevant information and

---

158. That Act imposes treble damages and civil penalties upon persons who submit false monetary claims to the federal government. See 31 U.S.C. § 3729(a) (2000). Suits under the Act can be brought either by the Attorney General or by a private person “in the name of the Government.” *Id.* § 3730(a)-(b). The Act’s growing use against asserted health care fraud has engendered controversy. See, e.g., Joan H. Krause, “Promises To Keep”: *Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363 (2002).

159. Cf. Evan Caminker, *The Constitutionality of Qui Tam Actions*, 99 YALE L.J. 341, 350 (1989) (noting, with respect to the False Claims Act, that “detecting fraud against the Federal treasury often is extremely difficult for the government without the aid of ‘informers,’” in part “because often the only persons who know about frauds are associated with the perpetrators . . . and are therefore reluctant to notify the authorities”).

160. Cf. *id.* at 350-51 (“[G]iven the ‘harsh reality of today’s funding limitations of . . . the budgets of the government’s prosecuting agencies,’ public officials often cannot commit the time and resources necessary for the successful prosecution of fraud even when they have already somehow managed to detect it.”).

161. Cf. *id.* at 351 (noting with respect to the False Claims Act that “[g]overnment agencies may be sufficiently dependent upon (or co-opted by) specific players in the military-industrial complex that the desire to prosecute wrongdoers diligently is compromised”).

162. There would be no Article III standing bar to such a claim. See *infra* notes 269-270 and accompanying text.

decide whether to pursue the action on its own behalf, either through litigation or an administrative proceeding.<sup>163</sup> As discussed below, this early review not only would provide the government with early input on the suit, it also would alert the FDA to the possible existence of a safety problem. Even if the government decided not to press the civil claim, this early warning could spur other investigative action within the FDA.

If the government did not take over the case, it would still retain some supervisory control. It could require the relator to provide it with copies of pleadings and with relevant information gained through discovery.<sup>164</sup> If it changed its decision later in the litigation, it could seek to intervene at that point.<sup>165</sup> The government could obtain dismissal of the suit over the *qui tam* relator's objection by establishing good cause for the dismissal (as in the case of a demonstrably frivolous claim).

This distribution of power over the prosecution of the suit would balance two competing concerns. On one hand, the value of the *qui tam* system comes from the opportunity for a private party to press a *qui tam* claim despite government inaction. Such inaction may sometimes arise from an agency's unwillingness to press a claim that would reveal evidence of prior agency errors or that would disadvantage an influential company. In the light of these concerns, it would be desirable to place some constraints on the government's ability to secure dismissal of the suit over the relator's objection. On the other hand, it is possible that if the government's ability to obtain dismissal of the suit were too constrained, courts might find that the mechanism offended separation of powers principles.<sup>166</sup> If a requirement that the government show good cause for the

---

163. The False Claims Act requires the relator to provide the United States with "[a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses." 31 U.S.C. § 3730(b)(2) (2000). The United States then has at least sixty days to decide whether to take over the action. *See id.* § 3730(b)(2)-(3). The government can press the claim either in the civil suit, *see id.* § 3730(b)(4)(A), or in an administrative proceeding, *see id.* § 3730(c)(5).

164. *Cf. id.* § 3730(c)(3) ("If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense).").

165. *Cf. id.* ("When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.").

166. *See infra* notes 275-279 and accompanying text. Constraints on the government's ability to control the suit might raise separation of powers questions, but should not raise any other constitutional problems. As discussed below, the standing of a *qui tam* relator to press the claim is supported by the notion that the government has assigned a part of its injury to the *qui tam* relator. *See infra* notes 269-72 and accompanying text. The strength of that rationale would not vary depending on the degree of government control of the suit, because the degree of government

dismissal were deemed to impinge improperly on the executive branch's authority, the standard could be changed to permit dismissal at the government's behest for any rational governmental reason.<sup>167</sup>

A successful relator would be paid a share of any damages recovery or settlement (but the relator would receive nothing if the defendant prevailed). The relator's share would vary depending on the degree of the relator's participation and the extent to which information provided by the relator played a role in the recovery.<sup>168</sup> The statute could also require a losing defendant to pay the relator's reasonable expenses, including attorney's fees.<sup>169</sup> The terms of judgments and

control would not alter the existence of a cognizable injury. Indeed, if anything, a *qui tam* relator's eagerness to press a claim (despite government skepticism) indicates that the relator is the sort of litigant who will litigate the claim zealously, which would subserve the presentation of the merits. Nor would it be persuasive to suggest that the degree of government control over the suit should affect the question of whether there is a Seventh Amendment right to a jury trial on the claim; the absence of government control over the suit would not create a right to a jury trial where none would otherwise exist.

167. The latter standard would parallel court interpretations of the False Claims Act, under which the government can "cause the action to be dismissed for any rational governmental reason, notwithstanding the *qui tam* plaintiff's desire that it continue." *United States ex rel. Stevens v. Vt. Agency of Natural Res.*, 162 F.3d 195, 202-03 (2d Cir. 1998), *rev'd on other grounds*, 529 U.S. 765 (2000).

168. In False Claims Act cases taken over by the government, the relator can only receive up to ten percent of the proceeds if the action was "based primarily" on information that was in the public record, but otherwise receives from fifteen to twenty-five percent, "depending upon the extent to which the person substantially contributed to the prosecution of the action." 31 U.S.C. § 3730(d)(1) (2000). In cases that the government decides not to take over, the relator receives from twenty-five to thirty percent of the proceeds. *See id.* § 3730(d)(2).

Some provision would need to be made for cases in which the relator had worked for the defendant. *Cf. id.* § 3730(d)(3) ("[I]f [the relator] planned and initiated the violation . . . the court may, to the extent the court considers appropriate, reduce the [relator's] share of the proceeds . . . , taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation"). On the one hand, current and former employees may have key information concerning product safety, and the scheme should provide an incentive to bring that information forward. *Cf., e.g., United States ex rel. Franklin v. Parke-Davis*, No. Civ. A.96-11651-PBS, 2003 WL 22048255, at \*1 (D. Mass. Aug. 22, 2003) (False Claims Act case in which relator alleged that his former employer "promoted the drug Neurontin for uses not approved by the Food and Drug Administration"). On the other, it would be unseemly to award a substantial portion of the damages to a person who had been responsible for the safety problem in the first place.

If the relator were one of those injured by the product, she would also receive a share of the damages distributed to injured claimants. *See infra* notes 176-178 and accompanying text.

169. *Cf.* 31 U.S.C. § 3730(d)(1)-(2) (2000). The False Claims Act provides that if the government does not take over the case and if the defendant wins, the court "may" require the

settlements in *qui tam* actions would be a matter of public record.<sup>170</sup>

Under the system sketched here, there might sometimes be competition among would-be relators and their counsel. The False Claims Act's *qui tam* system accords relator status to the first person or persons to file a particular *qui tam* claim, and excludes later *qui tam* suits concerning the same facts.<sup>171</sup> The first-to-file rule may make sense in the area of false claims, where the value added by the relator may lie primarily in the initial disclosure of the fraud.<sup>172</sup> But when the *qui tam* suit will settle the question of a product's safety—and the discovery and trial process may call for significant expertise—some safeguards should be imposed to ensure that the lawyers litigating the claim are experienced and competent.

Thus, a modified first-to-file rule could be employed: If more than one *qui tam* suit concerning the same facts is filed within a short time period, the actions could be consolidated in one district court, and the court could select an appropriate relator (or set of joint relators) and suitable counsel.<sup>173</sup> In evaluating

relator to pay the defendant's reasonable attorney fees, if the action was "clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." *Id.* § 3730(d)(4).

170. As discussed below, defendants may seek confidentiality when settling private lawsuits. *See infra* notes 351-353 and accompanying text. Secret settlements of *parens patriae* claims, however, would be inappropriate: In suits on behalf of the government, there is a legitimate public interest in the terms of a settlement. Accordingly, the opt-in system would require that the terms of settlements be public. For an explanation of the opt-in mechanism, see Section III.A below.

Such a requirement would not necessarily present a significant downside for defendants. The main reason why secret settlements appeal to defendants is that secrecy deprives other potential plaintiffs of useful information. Within the opt-in system, however, the likelihood of follow-on claims would be significantly reduced, because the claims of all existing claimants would be resolved in the settlement. Although publication of the terms of a settlement might generate adverse publicity and affect sales, it would not have a direct impact on the liability of a company within the opt-in system.

171. *See* 31 U.S.C. § 3730(b)(5) (2000) ("When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action."); *see also* JOHN E. CLARK, ETHICS ISSUES IN *QUI TAM* LITIGATION: SOME THOUGHTS FROM THE PERSPECTIVE OF A RELATOR'S COUNSEL, (A.B.A. Ctr. for Continuing Legal Educ., Nat'l Inst., N02CFCB ABA-LGLED I-1, 2001) ("It is not unusual for two or more individuals who share knowledge about a prospective defendant's actions—typically because they are co-workers—to join forces and seek to pursue a *qui tam* action jointly.").

172. *See United States ex rel. LaCorte v. Smithkline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998) ("[C]laimants alleging the same material facts as prior relators should not share in a *qui tam* award, because their allegations are unlikely to increase the total recovery.").

173. In some instances, would-be relators might include both an insider with information about the product and one or more persons injured by the product. The court would then face the task of selecting relators from among those persons. According relator status to a company whistleblower



proposed counsel for the relator, the court should consider, among other things, any work the lawyer has done to develop the potential claim, the lawyer's experience in relevant areas of product liability litigation, and the resources the lawyer can bring to the representation.<sup>174</sup> The selection of a relator and of the relator's attorney could be decoupled if necessary: For example, an industry insider who brought significant nonpublic information to the table, but who was represented by inexperienced counsel, could be directed to seek more experienced representation in order to be allowed to proceed as the *qui tam* relator.<sup>175</sup>

If, upon referral, the FDA found a safety problem, the district court would

---

would serve the goal of encouraging those with relevant information to come forward; on the other hand, according relator status to one or more injured claimants would help to ensure that the claimants' perspective is presented in the litigation. In at least some cases, the optimal choice would be to appoint multiple persons to act jointly as relators.

174. When appointing counsel in a federal class action:

[T]he court . . . must consider:

- the work counsel has done in identifying or investigating potential claims in the action,
- counsel's experience in handling class actions, other complex litigation, and claims of the type asserted in the action,
- counsel's knowledge of the applicable law, and
- the resources counsel will commit to representing the class.

FED. R. CIV. P. 23(g)(1)(C). The court may also consider other relevant factors. *See id.*

175. The Private Securities Litigation Reform Act of 1995 (PSLRA) provides a precedent for such "decoupling." In federal securities fraud class actions, the PSLRA directs the court to "appoint as lead plaintiff the member or members of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members ( . . . the 'most adequate plaintiff')." 15 U.S.C. § 78u-4(a)(3)(B)(i) (2000). In turn, "[t]he most adequate plaintiff shall, subject to the approval of the court, select and retain counsel to represent the class." *Id.* § 78u-4(a)(3)(B)(v). This provision, by "permit[ting] the plaintiff to choose counsel rather than have counsel choose the plaintiff," S. REP. NO. 104-98, at 11 (1995), *reprinted in* 1995 U.S.C.C.A.N. 679, was designed to lessen the influence wielded by plaintiffs' class action lawyers. And while the provision puts the initial choice of counsel in the hands of the "most adequate plaintiff"—an entity that will frequently turn out to be a large institutional investor—the statute preserves authority in the court "to approve or disapprove the lead plaintiff's choice of counsel when necessary to protect the interests of the plaintiff class." *Id.* at 12. The PSLRA has generated debate over the extent to which the court should override the lead plaintiff's preference concerning counsel. *See, e.g.*, Third Circuit Task Force Report on the Selection of Class Counsel, 208 F.R.D. 340, 345 (2002) ("The Act raises a number of questions, including the degree to which a court should defer to the lead plaintiff's choice of counsel and whether a court-sponsored auction is permissible in securities class actions."). But it seems clear that in at least some cases the PSLRA will decouple the choice of plaintiff from the choice of counsel.



proceed to apply the FDA's guidance on causation in order to determine or estimate the number of persons injured by the product. The amount of compensatory damages would depend on the number, type, and severity of injuries. Often, damages determinations could be made on the basis of individualized evidence; however, in the case of a product that harmed huge numbers of people, the court might use statistical methods to set damages amounts.<sup>176</sup> In determining appropriate damages, the court would also take into account factors relating to the defendant's culpability, including an assessment of the time when the safety issue first became known or knowable, and whether the company was proactive in discerning and addressing the issue.<sup>177</sup>

After determining damages, the court would enter judgment. The proceeds of the judgment would go into a compensation fund, which would be distributed by a special master to claimants based upon their exposure and injury.<sup>178</sup>

Because the *parens patriae* suit would assert the government's interest in obtaining redress on behalf of all those currently injured by a product, the judgment would determine the question of the company's liability with respect to current injuries. The judgment's finality, however, would be subject to two major limitations.

One limitation concerns "exposure-only" claimants—those persons who have used a product, but who have not yet shown signs of injury. The court's assessment of damages might include a component designed to cover the cost of compensation for claimants whose latent injuries only manifest themselves after judgment. However, if it turned out that the class of persons with latent injuries was larger than the court had anticipated, the government should be able to reopen the judgment to seek additional compensatory relief.

The other limitation concerns cases in which the FDA determines either that the product is safe or that causation is absent. Such a determination will result in

---

176. A number of commentators have discussed the possibility of determining damages on an aggregate basis in mass tort cases. See, e.g., Michael J. Saks & Peter David Blanck, *Justice Improved: The Unrecognized Benefits of Aggregation and Sampling in the Trial of Mass Torts*, 44 STAN. L. REV. 815 (1992); Richard A. Nagareda, *Turning from Tort to Administration*, 94 MICH. L. REV. 899, 917 (1996).

177. Subsection III.A.2 discusses in more detail the factors relevant to the damages determination. See *infra* text accompanying notes 323-333.

178. The details of the fund's administration would depend on a number of factors. In cases where the district court's damages calculations were based on individualized assessments of damages, the fund administrator would apply those individualized assessments in distributing payments to claimants. In cases where aggregate damages calculations were employed by the district court, the fund administrator would need to require some showing from each claimant concerning exposure to the product and degree of injury; the administrator could then employ a schedule or matrix to set the award for each claimant.

a judgment in favor of the defendant, and ordinarily that should be the end of the matter. However, in some instances, advances in science and research may uncover evidence concerning safety and causation that was unavailable at the time of the initial *qui tam* action, and such evidence may provide the quantum of proof that was lacking during the first proceeding. In those instances, the government (or, in appropriate circumstances, a *qui tam* relator) should be able to seek to reopen the judgment and relitigate the question of safety and causation. However, the standard for reopening the judgment would have to be fairly demanding—both for practical reasons and because of constitutional concerns.<sup>179</sup>

### *C. Comparing the Options*

In this Section, I will compare the options described above along various dimensions. Constitutional constraints impose some limits on the range of structural options among which policymakers may choose. Thus, I first consider whether each of the options detailed above is constitutionally permissible. It seems likely that the system of hybrid adjudication for private tort claims would face a Seventh Amendment barrier, but that the other three options could comport with the Constitution. I next compare the remaining three options—government enforcement within an agency setting, private intra-agency enforcement, and *qui tam* claims—by considering their likely effects on the cost and speed of litigation, the skill and zeal with which claims would be presented, and the expertise and neutrality of the decisionmaker. I argue that *qui tam* enforcement may be the most desirable, because it harnesses the skills of the private bar, and it provides the protections of an independent, generalist judicial decisionmaker.

---

179. David Shapiro has noted:

[T]he need to recognize the finality of judgments—their immunity from reopening or nullification at the hands of the executive or legislature (as well as the oft-repeated canon that the courts do not sit to render “advisory opinions”) is fundamental to the status of the federal courts under Article III of the Constitution . . . .

DAVID L. SHAPIRO, CIVIL PROCEDURE: PRECLUSION IN CIVIL ACTIONS 14 (2001). The contours of this constraint are uncertain because “[t]he Supreme Court has seldom had to consider how much res judicata effect is necessary.” RICHARD H. FALLON, JR. ET AL., HART AND WECHSLER’S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 105 (5th ed. 2003). It seems clear, however, that some latitude to reopen judgments is permissible. In civil actions, a federal court has discretion to grant relief from a judgment on the ground of “newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial,” if the relief is sought within a year after entry of judgment. FED. R. CIV. P. 60(b)(2). Although the system described in the text would be more lenient than Rule 60(b)(2) in at least some respects—for example, it would not include the one-year time limitation—it could presumably be designed so that the judgment in the initial suit would have enough finality to comport with Article III.

### 1. *Constitutional Constraints*

To the modern eye, regulation and litigation overlap. It is thus tempting to consider the various configurations—administrative adjudication, court adjudication, hybrid adjudication—from a purely functional perspective. The choice of structure, however, can have constitutional implications as well. In this Subsection, I review constitutional issues posed by each of the four schemes sketched above.<sup>180</sup> The internal-agency-enforcement model is clearly constitutional. The private-enforcement/agency-adjudication model may be constitutional as well. *Qui tam* claims in the hybrid system also pass constitutional scrutiny. Private claims in the hybrid system are questionable, however, because plaintiffs would likely have a Seventh Amendment right to a jury, and the referral of safety and causation issues to the FDA would likely violate that right.

It is useful, at the outset, to review the concerns that underlie the requirements set by Article III and the Seventh Amendment. Article III serves structural values: The requirement that many types of disputes be adjudicated by life-tenured, salary-protected judges maintains the function of the Article III courts and prevents the other two branches from aggrandizing themselves at the expense of the judiciary.<sup>181</sup> In addition, Article III protects the litigant's right to a fair, independent tribunal.<sup>182</sup> The Seventh Amendment protects individual rights by ensuring that disputes within its scope can be heard by juries, which can provide an independent check on government decisionmaking. The Court has

---

180. The schemes discussed here would operate prospectively: Companies could choose to opt in when submitting new products for FDA review, *see infra* Section III.A. Thus, the proposals considered in this Subsection would not apply to products already on the market, and thus would not affect any vested legal rights. The preemption of potential state tort claims therefore would not violate due process. *See* Olivia A. Radin, Note, *Rights as Property*, 104 COLUM. L. REV. 1315, 1328 (2004) ("The Supreme Court [has] found that laws that affect future actions do not implicate a property interest.").

181. As the Court has explained:

Article III, § 1, safeguards the role of the Judicial Branch in our tripartite system by barring congressional attempts 'to transfer jurisdiction [to non-Article III tribunals] for the purpose of emasculating' constitutional courts, *National Ins. Co. v. Tidewater Co.*, 337 U.S. 582, 644 . . . (1949) (Vinson, C.J., dissenting), and thereby preventing 'the encroachment or aggrandizement of one branch at the expense of the other.' *Buckley v. Valeo*, 424 U.S. 1, 122 . . . (1976) (per curiam).

*Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850 (1986).

182. *See id.* at 848 ("Article III, § 1's guarantee of an independent and impartial adjudication by the federal judiciary of matters within the judicial power of the United States . . . serves to protect primarily personal, rather than structural, interests.").

been protective of Seventh Amendment rights within the court system,<sup>183</sup> but has permitted Congress some latitude to render that Amendment inapplicable by assigning disputes to agencies instead of courts.<sup>184</sup>

*a) Internal Agency Enforcement*

The internal-agency-enforcement scheme is standard fare in the administrative state. "Congress has often created new statutory obligations, provided for civil penalties for their violation, and committed exclusively to an administrative agency the function of deciding whether a violation has in fact occurred."<sup>185</sup> Such an arrangement comports with Article III because government enforcement of civil penalties for violation of an administrative scheme falls within the traditional core of "public rights" cases that can be committed to non-Article III tribunals<sup>186</sup> (or, by extension, to administrative agencies with limited review in Article III courts<sup>187</sup>). And though a civil penalty defendant would have a right to a jury if the action took place in an Article III court,<sup>188</sup> no such right attaches when the penalty proceeding unfolds within an administrative agency.<sup>189</sup>

183. See *infra* note 240.

184. See *infra* note 239.

185. *Atlas Roofing Co. v. Occupational Safety & Health Review Comm'n*, 430 U.S. 442, 450 (1977).

186. See *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 64-69 (1982) (plurality opinion) (describing the requirement of Article III adjudication, and listing exceptions concerning territorial courts, courts-martial, and cases involving "public rights"). Although the Court has since held that the "public rights" category includes some disputes to which the government is not a party, see *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 586 (1985) ("Insofar as appellees interpret [prior cases] as establishing that the right to an Article III forum is absolute unless the Federal Government is a party of record, we cannot agree."), cases brought by or against the government continue to fall within the core of the "public rights" doctrine.

187. See *N. Pipeline*, 458 U.S. at 67 n.18 (plurality opinion) ("Congress' power to create legislative courts to adjudicate public rights carries with it the lesser power to create administrative agencies for the same purpose, and to provide for review of those agency decisions in Art. III courts.").

188. See *Tull v. United States*, 481 U.S. 412, 420 (1987) (stating that an action for civil penalties under Clean Water Act "is clearly analogous to the 18th-century action in debt, and federal courts have rightly assumed that the Seventh Amendment required a jury trial").

189. As the *Atlas Roofing* Court explained:

[W]hen Congress creates new statutory 'public rights,' it may assign their adjudication to an administrative agency with which a jury trial would be incompatible, without violating the Seventh Amendment's injunction that jury trial is to be 'preserved' in 'suits at common law.' . . . This is the case even if the Seventh Amendment would have

*b) Private Intra-Agency Enforcement*

The constitutionality of the private intra-agency enforcement proceeding would depend on whether the rationales described above, with respect to government enforcement, could extend to private claims in the context of the FDA regulatory scheme. Taken together, two cases—*Thomas v. Union Carbide Agricultural Products Co.*<sup>190</sup> and *NLRB v. Jones & Laughlin Steel Corp.*<sup>191</sup>—suggest that the scheme could be permissible. But because both of these cases are distinguishable from the FDA products liability proposal, the proposal's constitutionality is not entirely free from doubt.

In *Thomas* the Court held that the “public rights” doctrine extends to some disputes between private parties. *Thomas* concerned a pesticide maker's right to compensation when its data were used to facilitate regulatory approval (under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”)) of a competitor's similar pesticide.<sup>192</sup> Disagreements between pesticide makers over the appropriate amount of compensation were sent to binding arbitration, with very limited federal court review.<sup>193</sup> In rejecting a participant's Article III challenge to the scheme, the Court held that the pesticide maker's right to compensation was “not a purely ‘private’ right,” because it had “many of the characteristics of a ‘public’ right.”<sup>194</sup> In particular, the use of the pesticide data played “an integral part” in “a complex regulatory scheme” to protect public health.<sup>195</sup>

Private intra-agency enforcement of claims for violation of FDA requirements would arguably fall within the *Thomas* Court's statement that “Congress, acting for a valid legislative purpose pursuant to its constitutional powers under Article I, may create a seemingly ‘private’ right that is so closely integrated into a public regulatory scheme as to be a matter appropriate for

---

required a jury where the adjudication of those rights is assigned instead to a federal court of law instead of an administrative agency.

*Atlas Roofing*, 430 U.S. at 455. For a critique of this distinction, see Ellen E. Sward, *Legislative Courts, Article III, and the Seventh Amendment*, 77 N.C. L. REV. 1037, 1140 (1999) (“To allow Congress to avoid the Seventh Amendment by assigning adjudication of certain matters otherwise meeting the constitutional test for the Seventh Amendment to non-Article III courts is tantamount to informally amending the Constitution to limit the reach of the Seventh Amendment.”).

190. 473 U.S. 568 (1985).

191. 301 U.S. 1 (1937).

192. See *Thomas*, 473 U.S. at 571-73.

193. See *id.* at 573-74 (“The arbitrator's decision is subject to judicial review only for ‘fraud, misrepresentation, or other misconduct.’”).

194. *Id.* at 589.

195. *Id.*



agency resolution with limited involvement by the Article III judiciary.”<sup>196</sup> As in *Thomas*, the private claims adjudication would play an integral role in the FDA’s regulatory scheme: Private claims would help to enforce FDA requirements, would provide information to assist the FDA in its regulatory role, and would result in compensation for those injured by safety problems.

However, some key differences could limit the application of *Thomas*’ holding to the scheme described here. The *Thomas* Court emphasized that those involved in FIFRA’s compensation scheme were “voluntary participants in the program.”<sup>197</sup> As explained below,<sup>198</sup> potential defendants in the FDA enforcement scheme could validly consent to the system in advance. However, the claimants in the private enforcement scheme would be people injured by medical products; those claimants would not have meaningfully consented to the use of the non-Article III system.<sup>199</sup>

In *Thomas*, the Court also found it significant that the rights at issue were federal rights that did not “depend on or replace a right to . . . compensation under state law.”<sup>200</sup> In the FDA enforcement scheme, although the claim would arise under federal law, it would substantially resemble (and supplant) state tort claims for products liability. To the extent that federal rights that displace similar state common law causes of action fall closer to the core of Article III concerns,<sup>201</sup> this difference might cut against extending *Thomas* to the FDA

196. *Id.* at 593-94.

197. *Id.* at 589; *see also id.* at 592 (“[U]nder FIFRA, the only potential object of judicial enforcement power is the follow-on registrant who explicitly consents to have his rights determined by arbitration.”).

198. *See infra* Section III.A (discussing opt-in mechanism); *see also infra* note 268.

199. Perhaps it could be argued that by using a medical product (labeled with an announcement of the administrative compensation scheme) one consents in advance to the use of the non-court, non-jury proceeding. However, there are serious questions as to the practicality and fairness of such a position. *Cf.* Sage, *supra* note 46, at 990 (noting, with respect to treatment decisions involving drugs, that “[m]any consumers are under physical and emotional burdens that may preclude true freedom of choice”).

200. *Thomas*, 473 U.S. at 584.

201. As the *Thomas* Court explained:

In assessing the degree of judicial involvement required by Article III in this case, we note that the statute considered in *Crowell* [v. Benson, 285 U.S. 22 (1932)] is different from FIFRA in significant respects. Most importantly, the statute in *Crowell* displaced a traditional cause of action and affected a pre-existing relationship based on a common-law contract for hire. Thus it clearly fell within the range of matters reserved to Article III courts under the holding of *Northern Pipeline*. See 458 U.S., at 70-71 n.25 (plurality opinion) (noting that matters subject to a “suit at common law or in equity or admiralty” are at “protected core” of Article III judicial powers); *id.*, at 90 (opinion concurring in judgment) (noting that state law contract actions are “the stuff of the traditional actions

enforcement scheme.

This is not to say that claims replacing state-law causes of action can never be assigned to agencies for adjudication. *CFTC v. Schor*<sup>202</sup> demonstrates that even state-law claims can be heard by federal agencies in some circumstances. *Schor* addressed a scheme whereby customers injured by a commodity broker's violation of federal law could seek reparations in a proceeding before the Commodity Futures Trading Commission ("CFTC").<sup>203</sup> CFTC regulations permitted a broker to assert factually related counterclaims in the reparations proceeding.<sup>204</sup> Although such counterclaims were state law claims "of the kind assumed to be at the 'core' of matters normally reserved to Article III courts,"<sup>205</sup> the Court upheld the scheme.

The *Schor* Court relied upon two factors that could apply with equal strength to the FDA scheme. First, the Court emphasized that the CFTC's jurisdiction over state-law counterclaims was necessary to the success of the regulatory scheme.<sup>206</sup> If, as I have argued, private enforcement is a necessary supplement to FDA regulation, then the claim of regulatory necessity could similarly support the permissibility of the FDA adjudicatory scheme. Second, the Court noted that the CFTC's jurisdiction was limited to a particular field—claims concerning violations of federal commodities laws, plus factually related claims—rather than extending to all sorts of state-law claims.<sup>207</sup> Likewise, the FDA enforcement scheme would only concern claims regarding injury from certain FDA-regulated products.

However, *Schor*, even more than *Thomas*, turned upon the notion of consent.<sup>208</sup> *Schor* stands for the proposition that the assignment of a private-rights

at common law tried by the courts at Westminster in 1789").

*Thomas*, 473 U.S. at 587.

202. 478 U.S. 833 (1986).

203. See *Schor*, 478 U.S. at 836.

204. See *id.* at 837.

205. *Id.* at 853.

206. See *id.* at 856 ("It was only to ensure the effectiveness of [the reparations] scheme that Congress authorized the CFTC to assert jurisdiction over common law counterclaims. Indeed . . . absent the CFTC's exercise of that authority, the purposes of the reparations procedure would have been confounded.").

207. See *id.* at 852-53 ("The CFTC . . . deals only with a 'particularized area of law,' . . . whereas the jurisdiction of the bankruptcy courts found unconstitutional in *Northern Pipeline* extended to broadly 'all civil proceedings arising under title 11 or arising in or related to cases under title 11.'" (citation omitted)).

208. As the Court emphasized:

Schor indisputably waived any right he may have possessed to the full trial of Conti's counterclaim before an Article III court. Schor expressly demanded that Conti proceed

dispute to a non-Article III tribunal need not offend *structural* Article III concerns, so long as *Schor*'s balancing test is met.<sup>209</sup> But since the litigant in *Schor* had consented to submit the claim to the CFTC, the holding in *Schor* did not extend to cases in which no such waiver had occurred. In a subsequent case, *Granfinanciera, S.A. v. Nordberg*,<sup>210</sup> the Court held that in the absence of litigant consent, a private-rights claim that would carry a jury right if litigated in federal court is not assignable to a non-Article III tribunal for juryless adjudication.<sup>211</sup> The *Granfinanciera* Court explicitly equated the scope of the Seventh Amendment constraint with that of the Article III constraint.<sup>212</sup> Thus, though *Schor* indicates that private-rights disputes may be assigned to non-Article III tribunals when the litigants consent, *Granfinanciera* indicates that absent litigant consent, a case must fall within the public-rights category (or another traditional exception)<sup>213</sup> in order to be validly assigned to a non-Article III tribunal.<sup>214</sup>

In that respect, *Jones & Laughlin Steel* may provide more support for the private intra-agency enforcement scheme, because it did not involve litigant consent. Assuming that *Jones & Laughlin Steel*'s holding concerning the appropriateness of agency adjudication is still good law—a fair assumption,

---

on its counterclaim in the reparations proceeding rather than before the District Court, and was content to have the entire dispute settled in the forum he had selected until the ALJ ruled against him on all counts; it was only after the ALJ rendered a decision to which he objected that Schor raised any challenge to the CFTC's consideration of Conti's counterclaim.

*Id.* at 849 (citation omitted).

209. *See id.* at 851 (explaining that factors to be weighed include the degree to which the "essential attributes of judicial power" are reserved to Article III courts, and, conversely, the extent to which the non-Article III forum exercises the range of jurisdiction and powers normally vested only in Article III courts"; "the origins and importance of the right to be adjudicated"; and Congress's reasons for "depart[ing] from the requirements of Article III").

210. 492 U.S. 33 (1989).

211. *See id.* at 53-54.

212. *See id.*

213. In addition to the public rights doctrine, traditional exceptions that justify assignment of a matter to a non-Article III tribunal include matters assigned to territorial courts and to courts martial. *See N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 64-66 (1982).

214. *Granfinanciera* does tacitly suggest that a private rights claim that would carry a jury right if litigated in federal court could be sent to a non-Article III tribunal if that tribunal employed a jury and acted merely as an adjunct to an Article III court. The existence of such a possible exception explains why the Court in *Granfinanciera*, having determined that the claim at issue was a private rights claim, nonetheless left open the question whether bankruptcy judges (who are not Article III judges) could conduct a jury trial on the claim, subject to district court oversight. *See Granfinanciera*, 492 U.S. at 64. But the juryless adjudication of private claims within an agency setting obviously would not fit within that possible exception.

given that the Court has made no suggestion to the contrary—the case must now be read to rest upon the conclusion that the claim at issue fell within the public rights doctrine. Thus, the private intra-agency enforcement scheme could be validated as a public-rights scheme if it were considered sufficiently similar to the scheme at issue in *Jones & Laughlin Steel*.

In that case, a union instituted a proceeding against an employer before the NLRB seeking both injunctive remedies and back pay under federal law.<sup>215</sup> Among other objections, the employer asserted that it had a Seventh Amendment right to a jury trial on the back pay issue.<sup>216</sup> Though the Court rejected this contention partly because it viewed the back pay award as merely incidental to the injunctive relief,<sup>217</sup> the Court also suggested that juryless adjudication within the NLRB was appropriate because the claims at issue were created by Congress: “The instant case is not a suit at common law or in the nature of such a suit. The proceeding is one unknown to the common law. It is a statutory proceeding.”<sup>218</sup> Since consent was not a basis for the holding in *Jones & Laughlin Steel*, that case may support the constitutionality of the scheme outlined here. On the other hand, the case is not directly on point because it is somewhat difficult to argue that a claim for products liability is “unknown to the common law.”

In addition, *Thomas* and *Jones & Laughlin Steel* may also be distinguishable from the FDA scheme outlined here in that both cases involved decisionmakers relatively insulated from the executive branch: *Jones & Laughlin Steel* involved the NLRB, an independent agency, and in *Thomas*, the arbitrators were appointed by a separate, independent federal agency.<sup>219</sup> Although the FDA Commissioner must be confirmed by the Senate, he or she “serves at the pleasure of the . . . Secretary [of Health and Human Services] and, therefore, the President.”<sup>220</sup> Thus,

---

215. See *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 22 (1937). Because the union initiated the NLRB proceeding, the case can be viewed as one involving a dispute between private parties. It appears, however, that the actual disputants during the adjudication within the NLRB were the employer and the Board—not the union. See *id.* at 24-25 (describing proceedings before the NLRB).

216. See *id.* at 48.

217. See *id.* (holding that the Seventh Amendment “has no application to cases where recovery of money damages is an incident to equitable relief”).

218. *Id.*

219. See *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 574 n.1 (1985) (quoting statute that provided for appointment of arbitrator by Federal Mediation and Conciliation Service). *Schor* is similarly distinguishable: The Court noted that the CFTC, an independent agency, was viewed as “relatively immune from political pressures.” *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 855 (1986).

220. John W. Lundquist & Sandra L. Conroy, *Defending Against Food and Drug Prosecutions*, THE CHAMPION, July 1997, at 20, 20.

the FDA lacks some of the attributes of an independent agency.<sup>221</sup>

In sum, it seems possible that Congress could assign private claims under the FDCA to agency adjudication, but the answer is not entirely clear, because the boundaries of the “public rights” doctrine are incompletely defined.

### *c) Private Enforcement in a Hybrid System*

The immediately preceding analysis demonstrates that if a private claim under the FDCA is deemed to fall within the “public rights” doctrine, the claim can be adjudicated within the FDA without offending either Article III or the Seventh Amendment. But if such a claim is brought, instead, in federal court, and if the right and remedy involved are legal in nature, then a Seventh Amendment jury right attaches and this right would prevent referral of safety and causation issues to the FDA for binding determination.

It should be noted that Article III itself would not pose a barrier to the private/hybrid scheme. Even if private claims under the FDCA did not fall within the “public rights” doctrine, Article III would pose no bar to the adjudication of those claims in federal court with referral of the safety and causation issues to the FDA. From the perspective of Article III analysis, the private/hybrid scheme conforms well to the “adjunct” model exemplified by *Crowell v. Benson*.<sup>222</sup>

In *Crowell*, the Court considered a workers’ compensation scheme devised by Congress as a substitute for traditional federal negligence law in admiralty jurisdiction.<sup>223</sup> Under the scheme, claims for compensation were heard and determined by deputy commissioners within the United States Employees’ Compensation Commission.<sup>224</sup> Enforcement of any resulting compensation order was to be sought in federal court.<sup>225</sup> Though the court would review the administrator’s legal determinations de novo,<sup>226</sup> the administrator’s factual determinations generally were reviewed only under a deferential “supported by

221. See Paul R. Verkuil, *The Purposes and Limits of Independent Agencies*, 1988 DUKE L.J. 257, 259 (noting that agency independence typically involves “three statutory arrangements: the bipartisan appointment requirement; the fixed term requirement; and the requirement that removal be limited to express causes”).

222. 285 U.S. 22 (1932).

223. See *id.* at 36-38 (explaining that federal Longshoremen’s and Harbor Workers Compensation Act “deals exclusively with compensation in respect of disability or death resulting ‘from an injury occurring upon the navigable waters of the United States’ if recovery ‘through workmen’s compensation proceedings may not validly be provided by State law’”).

224. See *id.* at 42-43 (describing hearing procedure).

225. See *id.* at 44.

226. See *id.* at 45 (“Rulings of the deputy commissioner upon questions of law are without finality.”).



evidence” standard.<sup>227</sup> However, as the Court interpreted the statutory framework,<sup>228</sup> it provided for independent judicial determination of facts relevant to the commission’s jurisdiction<sup>229</sup> or to constitutional rights.<sup>230</sup>

At the time, the Court viewed the “public rights” doctrine as extending only to cases in which the government was a party.<sup>231</sup> But though the dispute in *Crowell* was thus classified as a “private rights” case,<sup>232</sup> the Court upheld the statutory delegation of fact-finding to the agency: Even in private rights cases, the Court held, “there is no requirement that, in order to maintain the essential attributes of the judicial power, all determinations of fact in constitutional courts shall be made by judges.”<sup>233</sup> It sufficed, in *Crowell*, that independent federal court review was available with respect to jurisdictional and constitutional facts.<sup>234</sup>

The private/hybrid scheme fits comfortably within *Crowell*’s holding with respect to the requirements of Article III. As in *Crowell*, a federal statutory claim would replace a judicially developed cause of action. The field covered by the statute would be limited to medical products regulated by the FDA.<sup>235</sup> The referral of technical questions to the FDA would “furnish a prompt, continuous, expert, and inexpensive method for dealing with a class of questions of fact which are peculiarly suited to examination and determination by an administrative agency specially assigned to that task.”<sup>236</sup> And the FDA’s decisions would be subject to federal court review for compliance with the statutory scheme, though the FDA’s judgments on safety and causation would

---

227. *Id.* at 46.

228. The Court adopted the interpretation noted in the text in order to avoid the constitutional issues that would have arisen had it found that the statute required judicial deference to the commissioner with respect to jurisdictional and constitutional facts. *See id.* at 62 (“When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, . . . this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.”).

229. *See id.* at 63.

230. *See id.* at 60.

231. *See id.* at 50 (“[T]he distinction is at once apparent between cases of private right and those which arise between the government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments.”).

232. *See id.* at 51 (“The present case does not fall within the categories just described, but is one of private right, that is, of the liability of one individual to another under the law as defined.”).

233. *Id.*

234. *See id.* at 62.

235. *Cf. id.* at 54 (“The statute has a limited application, being confined to the relation of master and servant . . .”).

236. *Id.* at 46.

receive deference.

*Crowell*, however, does not settle the Seventh Amendment question: Because *Crowell* concerned a statutory replacement for a claim in admiralty—not a claim at common law—the Seventh Amendment was not at issue in the case.<sup>237</sup> The Seventh Amendment jury trial requirement applies to a claim under a federal statute if the right and remedy are legal in nature.<sup>238</sup> Admittedly, if such a claim falls within the “public rights” doctrine it can be relegated to administrative adjudication and the Seventh Amendment jury right will not apply in the administrative proceeding.<sup>239</sup> But if, instead, such a claim is brought in federal court, the Seventh Amendment requires a jury.<sup>240</sup>

Under this analysis, situating the federal products liability claim in federal court would trigger a Seventh Amendment right to jury trial. The claim would be analogous to a state-law tort claim for products liability and the remedies sought—compensatory and punitive damages—would fall within the category of legal relief.<sup>241</sup> Accordingly, the binding determination of safety and causation issues by the FDA would be impermissible, because it would violate the right to a jury trial.<sup>242</sup> Of course, the jury trial right is waivable; but though the defendant could validly waive the right in advance, the claimant would not have done so.<sup>243</sup>

237. See *id.* at 45 (“As the claims which are subject to the provisions of the Act are governed by [federal] maritime law . . . and are within the admiralty jurisdiction, the objection raised by the respondent’s pleading as to the right to a trial by jury under the Seventh Amendment is unavailing.”).

238. See *Curtis v. Loether*, 415 U.S. 189, 194 (1974) (“The Seventh Amendment does apply to actions enforcing statutory rights, and requires a jury trial upon demand, if the statute creates legal rights and remedies, enforceable in an action for damages in the ordinary courts of law.”).

239. See *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 42 n.4 (1989) (“If a claim that is legal in nature asserts a ‘public right,’ . . . then the Seventh Amendment does not entitle the parties to a jury trial if Congress assigns its adjudication to an administrative agency or specialized court of equity.”).

240. As the Court has explained, when a federal scheme contemplates “enforcement of statutory rights in an ordinary civil action in the district courts, where there is obviously no functional justification for denying the jury trial right, a jury trial must be available if the action involves rights and remedies of the sort typically enforced in an action at law.” *Curtis*, 415 U.S. at 195.

241. It would be possible to design a claim that sought solely equitable relief. For example, the statute could provide for restitution of money the company had derived from sales of a defective product. However, such a remedy would often not meet the goal of compensation, because the harm done by a defective product may exceed the profits a company derived from it. And such a remedy would not serve the purposes furthered by punitive damages, either.

242. See *Ex parte Peterson*, 253 U.S. 300, 314 (1920) (“A compulsory reference with power to determine issues is impossible in the federal courts because of the Seventh Amendment . . .”).

243. The waiver analysis here parallels that discussed in the previous Section with respect to individual Article III rights. See *supra* text accompanying notes 198-199.

Conceptualizing the referral scheme as an application of the primary jurisdiction doctrine would not remove the Seventh Amendment difficulty. The Supreme Court has not explicitly addressed Seventh Amendment constraints on the application of primary jurisdiction. The Court's silence is perhaps unsurprising, because many of the cases that have presented issues of primary jurisdiction involved no Seventh Amendment right—for example, because the lawsuit in question was brought in state rather than federal court,<sup>244</sup> or sought equitable rather than legal relief.<sup>245</sup> In other cases, a litigant who might have had a Seventh Amendment right failed to argue that claim to the Supreme Court as a bar to the application of the primary jurisdiction doctrine.<sup>246</sup>

The two Supreme Court primary jurisdiction cases that most directly presented a Seventh Amendment issue are inapposite to the question considered in this Article. In *Keogh v. Chicago & N.W. Ry. Co.*,<sup>247</sup> the plaintiff argued to the Court that he had a constitutional right to a jury trial on his claims for antitrust damages.<sup>248</sup> However, the court below had dismissed Keogh's antitrust claims because by the time those claims reached trial, the Interstate Commerce Commission had approved the rates challenged by the plaintiff.<sup>249</sup> Given this procedural history, the Supreme Court's holding that Keogh's action was

---

244. See, e.g., *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 239 (1959); *Tex. & Pac. Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 426 (1907).

245. See, e.g., *Bd. of R.R. Comm'rs v. Great N. Ry.*, 281 U.S. 412, 416 (1930) (suit to enjoin enforcement of state agency's rate-setting order); *U.S. Navigation Co. v. Cunard S.S. Co.*, 284 U.S. 474, 478 (1932) (suit to enjoin alleged antitrust violation); *Far E. Conference v. United States*, 342 U.S. 570, 571, 573 (1952) (suit by the United States to enjoin alleged antitrust violations).

246. See, e.g., *Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289 (1973) (claims for damages under Commodities Exchange Act and Sherman Act; in Supreme Court briefs, petitioner did not assert a right to jury trial as a basis for reversal); *Chi. Mercantile Exch. v. Deaktor*, 414 U.S. 113, 113-14 (1973) (per curiam) (deciding case for claims for damages under Commodities Exchange Act and Sherman Act without a merits briefing; certiorari briefs did not mention right to jury trial); *Andrews v. Louisville & Nashville R.R.*, 406 U.S. 320, 320-21, 324-25 (1972) (damages suit that had been removed from state to federal court; majority refused to address "[t]he constitutional issue discussed in the dissent" because the issue was not included in the petition for certiorari); *id.* at 331 (Douglas, J., dissenting) ("Under the First Amendment . . . [the plaintiff] is petitioning the Government 'for a redress of grievances' in the traditional manner of suitors at common law; and by the Seventh Amendment is entitled to a jury trial."); *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 64-65 (1970) (action for damages and declaratory relief that had been removed from state to federal court; Supreme Court briefs did not mention a jury trial right).

247. 260 U.S. 156 (1922).

248. See Brief and Argument for Plaintiff in Error at 13, 15, *Keogh v. Chi. & N.W. Ry.*, 260 U.S. 156 (1922) (No. 823).

249. See *Keogh*, 260 U.S. 156.

properly dismissed<sup>250</sup> does not provide support for the proposition that a claim carrying a right to a jury can be stayed pending referral of a jury question to an agency for decision; rather, *Keogh* can be seen as applying the principle (later explicitly adopted by the Court<sup>251</sup>) that a litigant can be precluded from relitigating an issue determined in a prior proceeding even if the prior proceeding was one in which there was no jury trial.

In *Carnation Co. v. Pacific Westbound Conference*,<sup>252</sup> the Court was asked to decide whether the Federal Maritime Commission's jurisdiction over shipping rates precluded a plaintiff from suing for antitrust damages arising from shipping conferences' implementation of rate agreements.<sup>253</sup> The plaintiff and defendants focused their Supreme Court briefs on the question of exclusivity: Did the Shipping Act (administered by the Federal Maritime Commission (FMC)) provide the sole avenue for challenging rate agreements, or could a plaintiff also bring an antitrust claim in federal court? The plaintiff argued that if the Shipping Act were construed to exclude the antitrust remedy, that construction would "improperly . . . deprive [the plaintiff] of a right to trial by jury."<sup>254</sup>

The FMC argued that the antitrust action should be stayed, rather than dismissed, so that the FMC could determine whether the rate agreements violated the Shipping Act.<sup>255</sup> The defendants disagreed, insisting that dismissal, rather than a stay, was the appropriate disposition.<sup>256</sup> The plaintiff, as well, continued to focus on the question of dismissal, and continued to argue that if the Shipping Act provided the exclusive remedy, that would violate the Seventh Amendment.<sup>257</sup> Though the plaintiff also contended that the legality of the rates

250. *See id.* at 163.

251. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 337 (1979).

252. 383 U.S. 213 (1966).

253. *See id.* at 215.

254. Petition for a Writ of Certiorari at 4, *Carnation Co. v. Pac. Westbound Conference*, 383 U.S. 213 (1966) (No. 20).

255. *See* Memorandum for the Federal Maritime Commission at 5-6, *Carnation Co.* (No. 657); Brief for the United States and the Federal Maritime Commission at 13, *Carnation Co.* (No. 20).

256. *See* Supplemental Brief in Opposition for Respondents, Far East Conference, and Members and Certain Former Members Thereof Named as Defendants at 4, *Carnation Co.* (No. 657); Supplemental Brief in Opposition for Respondent Pacific Westbound Conference at 6-7, *Carnation Co.* (No. 20); Brief for Respondent Pacific Westbound Conference at 10-11, *Carnation Co.* (No. 20).

257. *See* Petitioner's Brief at 7, 56-59, *Carnation Co.* (No. 20). Responding to this argument, one of the defendants asserted that limiting the plaintiff to the Shipping Act's administrative remedy would not violate the Seventh Amendment because the plaintiff sought "damages resulting from a statutory violation unknown at common law"—i.e., the plaintiff was asserting a public

need not first be determined by the FMC, it did not stress the Seventh Amendment in connection with this facet of its argument.<sup>258</sup>

Meanwhile, the FMC concluded that its approval of an earlier agreement did not encompass the rate agreements challenged in the plaintiff's antitrust suit, and that the latter agreements violated the Shipping Act.<sup>259</sup> In its reply brief, the plaintiff asserted that the FMC took the view that "any administrative questions presented that were for determination by the Commission . . . have been determined, and in such way that petitioner is entitled to pursue its [antitrust] litigation" (unless, as the defendants contended, the Shipping Act provided the only possible remedy).<sup>260</sup> Unsurprisingly, the plaintiff's reply brief raised no Seventh Amendment challenge to the application of the FMC's findings in its antitrust suit.<sup>261</sup> Thus, when the Supreme Court held in *Carnation* that the plaintiff's antitrust suit should be stayed "pending the final outcome of the Shipping Act proceedings" (because the FMC's decision had been appealed),<sup>262</sup> there was no reason for the Court to consider whether the Seventh Amendment posed any barrier to such a stay, and the Court did not mention the question.

The Supreme Court, then, has not established whether the primary jurisdiction doctrine can be applied to require referral of factual issues to an agency for binding determination when those issues arise in a federal lawsuit on claims for which there is a Seventh Amendment right to a jury trial. The few commentators to discuss the question have noted the existence of doubt.<sup>263</sup> There

---

rights claim, not a private rights claim. See Brief for Respondent Pacific Westbound Conference at 56 n.51, *Carnation Co.* (No. 20) (citing *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 22 (1937)). Another set of defendants similarly disputed the contention that excluding antitrust suits would violate the Seventh Amendment. See Brief for the Respondents Far East Conference at 48-49, *Carnation Co.* (No. 20).

258. See Petitioner's Brief at 24-25, *Carnation Co.* (No. 20). The plaintiff did state—in response to the contention that the outcomes of jury trials on antitrust claims might vary from case to case—that "[i]f the results turn out to be not entirely consistent, but still sustainable, that must be laid to the workings of the Seventh Amendment." *Id.* at 79. This brief mention, however, did not present a clear argument that a stay, as opposed to dismissal, of the antitrust claims would violate the Seventh Amendment.

259. See *Carnation Co.*, 383 U.S. at 223 n.6.

260. Petitioner's Reply Brief at 9, *Carnation Co.* (No. 20).

261. See *id.*

262. *Carnation Co.*, 383 U.S. at 223-24.

263. See, e.g., Robert B. von Mehren, *The Antitrust Laws and Regulated Industries: The Doctrine of Primary Jurisdiction*, 67 HARV. L. REV. 929, 963 (1954) (noting that "at least in jury cases, there appears to be an insurmountable obstacle—the Seventh Amendment—to making an agency's findings of fact conclusive"); 5 JACOB A. STEIN ET AL., *ADMINISTRATIVE LAW* § 47.03[2] (2004) ("It has been argued that a court which refers to an agency questions of fact, as opposed to questions of law, should not be bound by the agency's decision because of the Seventh



seems to be no persuasive reason to distinguish such cases from any other instance in which a federal court contemplates referring a fact issue to a non-jury decisionmaker for binding determination; and the Court has made clear that the Seventh Amendment bars such referrals.<sup>264</sup> Accordingly, it appears likely that private enforcement within the hybrid system could founder upon the Seventh Amendment difficulty.<sup>265</sup>

---

Amendment's guarantee of a right to trial by jury.") (citing von Mehren).

264. See *supra* note 242. It should be noted that other possible applications of the primary jurisdiction doctrine (or similar schemes) can be permissible, even as to plaintiffs who would have a right to a jury trial if they were permitted to sue in federal court. Thus, for example, Congress can preempt a common law claim for damages (and leave persons injured in the future without a remedy) without violating the Seventh Amendment. See Nagareda, *supra* note 15, at 354 n.288. Also, Congress can provide that a "public rights" claim for damages falls within the exclusive jurisdiction of an agency, such that the claim must be dismissed if it is brought in federal court. Such an arrangement would relegate the claim to decision by the agency without a jury, but, as discussed above, this would not violate the Seventh Amendment. See *supra* note 239 and accompanying text. However, if Congress instead attempts to provide that the "public rights" damages claim can be brought in federal court, but that certain fact issues must be referred to the agency for binding decision, the plaintiff would have a Seventh Amendment right to a jury trial and the referral would violate that right. See *supra* note 240 and accompanying text.

265. To avoid impairing the jury trial right, Congress could provide for a jury trial and direct that the FDA render an advisory opinion that could persuade, rather than bind, the jury. Such a system could assist the jury in determining difficult issues, but because the jury would retain the ability to reject the panel's findings, the system would not ensure uniformity, and it might not gain the confidence of potential defendants.

Another possible argument is that there should be a "complexity exception" to the Seventh Amendment: Some commentators contend that as to highly complex issues requiring technical or scientific expertise, there should be no jury trial right. See, e.g., Graham C. Lilly, *The Decline of the American Jury*, 72 U. COLO. L. REV. 53, 80 (2001) (arguing that a complexity exception "seems especially appropriate . . . when a forthcoming trial is likely to be protracted and involve difficult technical or scientific issues"). But though at least one appellate court has endorsed such an exception, see *In re Japanese Elec. Prods. Antitrust Litig.*, 631 F.2d 1069, 1086 (3d Cir. 1980) (balancing due process and Seventh Amendment rights and finding "the most reasonable accommodation . . . to be a denial of jury trial when a jury will not be able to perform its task of rational decisionmaking with a reasonable understanding of the evidence and the relevant legal standards"), other courts have rejected it, see, e.g., *In re U.S. Fin. Sec. Litig.*, 609 F.2d 411, 431 (9th Cir. 1979) ("Not only do we refuse to read a complexity exception into the Seventh Amendment, but we also express grave reservations about whether a meaningful test could be developed were we to find such an exception."), and the Supreme Court has not yet resolved the dispute. Admittedly, an issue can be given to the judge rather than the jury—despite the fact that the issue arises in a case involving a jury right—if the issue is not one that was historically reserved for the jury and if the relative capabilities of juries and judges tilt the policy analysis in favor of judicial determination. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)

*d) Qui Tam Claims in a Hybrid System*

Maintenance of a *parens patriae* suit by a *qui tam* relator, by contrast, would both comport with Article III and avoid the Seventh Amendment problem.

A *qui tam* suit within the hybrid system would comply with Article III under *Crowell's* "adjunct" test, for the same reasons discussed in the preceding Section.<sup>266</sup> Indeed, the Article III argument in favor of the hybrid system would be even stronger in the *qui tam* context, because the suit, brought on behalf of the United States, would all the more clearly fall within the "public rights" doctrine.

A defendant ordinarily would have a Seventh Amendment jury right regarding *qui tam* claims brought within the hybrid system; the fact that the claim was brought in the government's name would not change the analysis.<sup>267</sup> However, as discussed in Section III.A, the defendant would waive that right in advance, when it opted into the federal products liability system.<sup>268</sup> (It would, in any event, be an unusual products liability defendant that complained of being deprived of a jury trial.) And because the *qui tam* relator would be pressing a claim on behalf of the government, Congress could, in the statutory scheme, waive any right to a jury trial on the relator's behalf.

Admittedly, use of the *qui tam* mechanism would introduce some additional constitutional issues. But though the *qui tam* mechanism has been challenged on both Article II and Article III grounds, the more persuasive view holds that it is constitutional. The Supreme Court rejected the Article III challenge in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*,<sup>269</sup> when it held that "a *qui tam* relator under the [False Claims Act] has Article III standing."<sup>270</sup>

(holding that "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court"). It is far from clear, however, that issues of safety and causation in a products liability case would meet this test.

266. See *supra* notes 222-236 and accompanying text.

267. See *Tull v. United States*, 481 U.S. 412, 420 (1987).

268. The proposal outlined here could hardly be viewed as impermissibly coercive. After all, the traditional baseline presumption is that states can regulate products that affect health and safety, and that such regulation can be accomplished through the tort system. Accordingly, a system that permits companies to opt in to an alternative system (or to opt out, and be subject to state-law tort claims) benefits the company by expanding its choices. Cf. Seth F. Kreimer, *Allocational Sanctions: The Problem of Negative Rights in a Positive State*, 132 U. PA. L. REV. 1293, 1300-01 (1984) (arguing that in assessing the permissibility of governmental allocations of benefits, courts should distinguish threats—i.e., "allocations that make a citizen worse off than she otherwise would be because of her exercise of a constitutional right"—from offers—i.e., allocations that "merely expand her range of options, leaving the citizen better off").

269. 529 U.S. 765 (2000).

270. *Id.* at 778. The Court cited "the doctrine that the assignee of a claim has standing to assert

However, the *Stevens* majority declined to address “whether *qui tam* suits violate Article II, in particular the Appointments Clause of § 2 and the ‘take Care’ Clause of § 3.”<sup>271</sup>

The Appointments Clause vests the President with power to appoint federal officers with the advice and consent of the Senate, but provides that Congress may vest the appointment of “inferior” officers “in the President alone, in the Courts of Law, or in the Heads of Departments.”<sup>272</sup> Some have argued that the False Claims Act’s *qui tam* provision violates this clause by permitting *qui tam* relators to function as federal officers without an appropriate appointment.<sup>273</sup> *Qui tam* relators, however, should not be viewed as “officers,” because they have no established position, they draw no salary, and they serve their function on an ad hoc basis.<sup>274</sup>

The Take Care Clause provides that the President shall “take Care that the Laws be faithfully executed.”<sup>275</sup> Though it is not entirely clear whether this clause vests power in the President or instead imposes a duty,<sup>276</sup> under either interpretation the clause should pose no problem for *qui tam* provisions. It seems clear that in cases where the government intervenes in a *qui tam* suit, the *qui tam* mechanism does not impair the government’s law-enforcement functions.<sup>277</sup> And because the executive branch retains significant control over a *qui tam* suit even in cases where the government chooses not to intervene,<sup>278</sup> the more persuasive

---

the injury in fact suffered by the assignor,” and reasoned that the False Claims Act “can reasonably be regarded as effecting a partial assignment of the Government’s damages claim.” *Id.* at 773.

271. *Id.* at 778 n.8.

272. U.S. CONST. art. II, § 2, cl.2.

273. See Richard A. Bales, *A Constitutional Defense of Qui Tam*, 2001 WIS. L. REV. 381, 430-33 (reviewing Appointments Clause arguments concerning *qui tam* mechanism).

274. See *United States ex rel. Stone v. Rockwell Int’l Corp.*, Nos. 99-1351, 99-1352, 99-1353, 2004 WL 433235, at \*17-\*18 (10th Cir. Mar. 5, 2004) (finding *qui tam* relators do not fall within Appointments Clause because they are not federal officers); *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749, 757-58 (5th Cir. 2001) (en banc) (same); *United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994) (same); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 759 (9th Cir. 1993) (same); Bales, *supra* note 273, at 430-33 (reviewing reasons why *qui tam* relators should not fall within scope of Appointments Clause).

275. U.S. CONST. art. II, § 3.

276. See, e.g., Caminker, *supra* note 159, at 356 (“The Supreme Court has suggested occasionally that the ‘take Care’ clause vests the President with prosecutorial discretion over Federal law enforcement, but this clause is better viewed as a mandate to follow the will of Congress than as a grant of exogenously defined power.”).

277. See *Stone*, 2004 WL 433235, at \*19 (rejecting the “contention that the presence of a *qui tam* relator in the litigation so hindered the Government’s prosecutorial discretion as to deprive the Government of its ability to perform its constitutionally assigned responsibilities”).

278. See *supra* notes 164-167 and accompanying text.

view holds that those cases do not violate the Take Care Clause either.<sup>279</sup>

Constitutional considerations, then, would likely eliminate one of the four options: The Seventh Amendment would probably bar the implementation of the private claim/hybrid adjudication model.<sup>280</sup> In the Subsection that follows, I will compare the merits, from a policy standpoint, of the three remaining options.

## 2. Policy Considerations

The *qui tam*/hybrid scheme appears to be the most attractive of the remaining possibilities for linking litigation with the regulatory system. Considerations of cost and speed are inconclusive; however, the quality of decisionmaking and the quality of advocacy in the *qui tam* system would be better, on balance, than those in systems that relied upon agency adjudication of either government or private claims.

---

279. See *Riley*, 252 F.3d at 757 (“Any intrusion by the *qui tam* relator in the Executive’s Article II power is comparatively modest, especially given the control mechanisms inherent in the FCA to mitigate such an intrusion and the civil context in which *qui tam* suits are pursued.”); *Taxpayers Against Fraud*, 41 F.3d at 1041 (explaining in dictum that *qui tam* suits in which the government does not intervene do not contravene separation of powers principles because the government retains means of controlling *qui tam* suits even if it chooses not to intervene); *Kelly*, 9 F.3d at 755 (“[T]he Executive Branch exercises at least an equivalent amount of control over *qui tam* relators as it does over independent counsels. Thus, the FCA gives the Attorney General sufficient means of controlling or supervising relators to satisfy separation of powers concerns.”); see also Bales, *supra* note 273, at 435 (“Comparing the *qui tam* provisions of the FCA to the independent counsel provisions upheld in *Morrison v. Olson*, 487 U.S. 654 (1988)] presents the strongest argument as to why judicial branch involvement in *qui tam* actions does not violate separation of powers principles.”); Bucy, *supra* note 152, at 956 (suggesting that “because an effective private justice model brings an invaluable and otherwise unobtainable resource to public regulatory efforts, namely inside information, the executive branch is unable to ‘take Care’ that laws are faithfully executed without such a model”).

Objections to *qui tam* suits have also been based on separation of powers more generally; these arguments, too, should be rejected. See, e.g., *Kelly*, 9 F.3d at 755-56 (rejecting the contention that “the *qui tam* provisions disrupt the proper balance of power between the three branches by permitting the Judicial Branch to encroach on executive authority”); Bales, *supra* note 273, at 435 (arguing that “because *qui tam* disperses power among the citizens rather than concentrating it in the hands of a single political branch, the principles underlying the separation of powers doctrine are not threatened as they are when, for example, Congress seeks to retain the power constitutionally apportioned to another branch”).

280. This assumption is based on the likelihood that the proposed scheme would not fall within any possible “complexity” exception to the Seventh Amendment. See *supra* note 265.



*a) Cost and Speed*

The agency-adjudication options might produce some cost savings relative to the hybrid-adjudication options, but the additional cost of hybrid adjudication should be weighed against its benefits.<sup>281</sup>

Agency adjudication might cut the costs of litigation if it provided a narrower range of discovery than is customary in civil litigation. Though some agencies provide for a range of discovery similar to that available in federal court,<sup>282</sup> the rules of other agencies “may severely restrict access to discovery.”<sup>283</sup> The FDA’s rules for civil penalty proceedings, for example, permit depositions only upon a showing of necessity and then only for the purpose of preserving testimony.<sup>284</sup>

Such restrictions on discovery, however, would reduce the effectiveness of litigation as a way to uncover safety-related information. Depositions, for instance, can be a key tool to uncover internal policies and deliberations within a company.<sup>285</sup> The savings achieved by restricting discovery to narrower limits than those imposed in federal court would therefore come at a significant cost.

In the hybrid system, some additional delay might result from the referral process, but that delay need not be excessive. The referral would occur at a point in the process when discovery was complete, and summary judgment motion practice would have served to narrow and focus the issues prior to trial. Because the proceedings in the hybrid system would not involve a jury, the referral process would not cause undue disruption; proceedings can more readily be segmented in bench trials than in jury trials.<sup>286</sup>

281. Cf. Kevin M. Clermont & Theodore Eisenberg, *Litigation Realities*, 88 CORNELL L. REV. 119, 130 (2002) (“Delay is an unavoidable feature of life, and it is not an evil in itself. The only evil is excessive delay, where excessive means that the costs of delay outweigh its benefits.”).

282. See 4 STEIN ET AL., *supra* note 263, § 23.01[2], at 23-15 (“Agencies such as the Federal Trade Commission, the Federal Maritime Commission, and the Federal Communications Commission . . . have closely modeled their discovery rules on the Federal Rules [of Civil Procedure].”).

283. *Id.* § 23.01, at 23-28 (discussing the NLRB). “For example, N.L.R.B. rules do not permit depositions except for the purpose of preserving testimony, and then only when in the discretion of the regional director or administrative law judge good cause has been shown.” *Id.* at 23-28.

284. See *supra* text accompanying note 125.

285. See *infra* Subsection III.B.2.

286. Another factor that bears upon litigation costs concerns the possibility of multiple suits. Both the agency-enforcement and *qui tam* options would structure the dispute as a single proceeding; by contrast, private claims in the agency setting could proceed singly as well as in a class format. Because they would require the resolution of all claims in a single proceeding, the agency-enforcement and *qui tam* systems could, overall, prove more efficient—though they also



*b) Decisionmaking: Bias and Expertise*

A consideration that supports situating the proceeding in federal court is that the court could provide better decisionmaking than the agency with respect to discovery and damages. The agency's comparative advantage regarding technical and scientific questions does not extend to all other issues that would arise in product safety litigation.

The political influence of the pharmaceutical industry is widely noted.<sup>287</sup> Critics also charge that recent changes have rendered the FDA, in particular, more vulnerable to industry influence,<sup>288</sup> and that the agency, "although quick to approve drugs, . . . is slow to take them off the market when they prove dangerous."<sup>289</sup> Given that each of the options discussed here would accord the FDA significant power over industry liability, care should be taken, in crafting the system to improve the FDA's independence. As Marcia Angell suggests, measures could include enhanced public funding for the agency, as well as enforcement of conflicts prohibitions for those serving on the FDA's advisory committees.<sup>290</sup> Even assuming such measures were adopted, however, there would remain a risk that the FDA could unduly defer to the interest of industry players. It is therefore useful to assess the degree to which the options discussed here would protect against the possibility of agency capture.<sup>291</sup>

Despite the internal separation of functions within the FDA—which would insulate an FDA hearing officer to some extent from the other parts of the agency—that officer might be subject to some pressures to accommodate industry by limiting the nature and scope of discovery against a products liability

---

might prove more cumbersome—than individual private claims within the agency.

287. See, e.g., ANGELL, *supra* note 47, at 198 ("The pharmaceutical industry has by far the largest lobby in Washington . . . . According to the consumer advocacy group Public Citizen, from 1997 through 2002, the industry spent nearly \$478 million on lobbying."); *id.* at 200 ("In the 1999-2000 election cycle, drug companies gave \$20 million in direct campaign contributions plus \$65 million in 'soft' money."); Sheryl Gay Stolberg & Gardiner Harris, *Re-Examining Medicare—The Drug Industry's Muscle: Industry Fights To Put Imprint on Drug Bill*, N.Y. TIMES, Sept. 5, 2003, at A1.

288. Marcia Angell has observed that the Prescription Drug User Fee Act, which seeks to speed the processing of drug applications by providing for payment of user fees, "makes the FDA dependent on an industry it regulates." ANGELL, *supra* note 47, at 208.

289. *Id.* at 209.

290. See *id.* at 243-44.

291. Obviously, federal courts could also be staffed with judges who are predisposed to favor industry defendants over products liability plaintiffs. However, Article III tenure protects judges from suffering repercussions as a result of decisions adverse to industry—which makes it likely that judges would be more willing, overall, to make such decisions.

defendant.<sup>292</sup> This might be especially true if the discovery in question had the potential to embarrass the agency—for example, by showing that the agency had failed adequately to respond to earlier evidence of safety concerns.<sup>293</sup> Indeed, David Graham, the Associate Director for Science in CDER's Office of Drug Safety, recently raised a very similar concern with respect to the FDA's current practice of postmarketing surveillance.<sup>294</sup> In the litigation context, permitting the plaintiff to develop evidence through discovery proceedings under the aegis of the court could prove a more effective information-gathering tool.

Of course, to the extent that there is agency bias of the sort suggested here, the problem will extend well beyond discovery. If the FDA's decisionmaking were unduly influenced by certain stakeholders, that could distort its review of safety and causation issues under the hybrid system as well. Such a concern may lead policymakers to reject any determinative role for the FDA in resolving tort claims, and I turn to that argument below. For the moment, it is significant to note that if policymakers were to grant the FDA a determinative role, the choice of institutional configuration would be important. Problems of FDA bias would be mitigated in the hybrid system by the fact that the record on which the agency made the safety and causation decisions would include evidence developed in a separate federal court proceeding. If that discovery process uncovered safety problems with a product, the resulting publicity could provide an inducement for the FDA to scrutinize the product carefully and to find liability where appropriate. By contrast, if the discovery process unfolded within the agency, a captured agency might prevent the plaintiff from ever developing certain evidence concerning liability.

Moreover, the reasons for submitting the safety and causation questions to the FDA do not extend to the discovery process. Even if it is taken as given that scientific and policy judgments concerning medical products should be left to FDA experts, there is nothing about the discovery process that requires a similar

292. Cf. McGarity, *supra* note 44, at 564 ("The very real possibility of agency capture by the regulated industry means that federal officials are not always eager to eliminate wrongful attempts to manipulate the regulatory process . . .").

293. Cf. Noah, *supra* note 66, at 503 (noting "the FDA's natural hesitancy to confess error when a drug it just approved generates unusual and unexpected rates of adverse reactions").

294. In testimony to a Senate committee, Graham warned:

[T]he new drug reviewing division that approved the drug in the first place and that regards it as its own child, typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues. The second greatest obstacle is often the senior management within the Office of Drug Safety, who either actively or tacitly go along with what the Office of New Drugs wants.

*Vioxx Hearings*, *supra* note 84 (statement of David J. Graham, Assoc. Dir. for Sci., Office of Drug Safety, FDA).

approach. Federal district judges and magistrate judges handle discovery disputes in complex litigation on a regular basis. They are expert at it. Indeed, there is some reason to think that a generalist district judge or magistrate judge might be better situated to handle discovery in a complex products liability case than a specialist hearing officer within the FDA: The experience that the generalist judge gains with discovery disputes in other types of cases could help to ensure that the discovery permitted in products liability litigation was calibrated at the level thought to be appropriate in general civil litigation.<sup>295</sup>

Similar considerations apply to the determination of damages. Once the FDA had settled the issue of safety and had provided guidance concerning the factors that should determine causation,<sup>296</sup> the federal court could handle the question of damages at least as competently as the agency. Indeed, the expertise gained by the court in assessing damages in other types of cases would provide a useful source of cross-pollination. There is also some reason to think that the FDA itself might prefer not to be tasked with determining damages. Such determinations are likely to be fraught with controversy, and the agency might well prefer to leave the question to a separate institution.<sup>297</sup>

### *c) Litigating: Incentives and Expertise*

The three proposals differ with respect to the entity pressing the claim as well as the entity deciding it. A comparison of the options therefore should consider the relative expertise of the litigator in each system, as well as that

---

295. Questions relating to the scope of, and limits on, discovery are not uncontroversial. See, e.g., Stephen B. Burbank & Linda J. Silberman, *Civil Procedure Reform in Comparative Context: The United States of America*, 45 AM. J. COMP. L. 675, 701 (1997) (noting that “[t]he responses of practicing lawyers to . . . the 1993 amendments to Rule 26 (discovery), were very seriously negative”); Thomas D. Rowe, Jr., *A Square Peg in a Round Hole? The 2000 Limitation on the Scope of Federal Civil Discovery*, 69 TENN. L. REV. 13 (2001) (critiquing the 2000 amendments to the discovery provisions in the Federal Rules of Civil Procedure). My point is merely that the experience with discovery in other types of complex litigation can profitably be applied to questions concerning discovery in products liability litigation concerning FDA-approved products; and situating the discovery process within the federal courts, rather than within the FDA, would make possible the application of that experience.

296. The FDA would determine the question of product safety—i.e., whether the product is safe enough to remain on the market and, if so, whether additional warnings are needed. In a case where the FDA found the product unsafe or the warnings inadequate, the FDA would also enumerate the factors that the district court should apply in order to determine specific causation—i.e., whether a particular claimant’s injury should be deemed to arise from the safety problem or inadequate warning.

297. Obviously, liability determinations would often be controversial as well. But the FDA’s relative expertise with respect to safety and causation issues would counterbalance this concern.

litigator's incentives to press valid claims. Under this analysis, the government-enforcement model may fare less well, both because the government's litigation resources would be limited<sup>298</sup> and because the private plaintiffs' bar may add useful expertise. By contrast, the *qui tam* proposal might help to ensure that claims are litigated by lawyers with appropriate expertise, and would provide structured incentives for industry insiders to bring forward nonpublic information concerning safety.

As noted above, the government-enforcement model would require Congress to dedicate significantly more resources to enforcement.<sup>299</sup> In theory, such a system could be financed by the private sector, through an ex ante system of user fees exacted during the product approval process<sup>300</sup> or through an ex post system of fee-shifting.<sup>301</sup> Such an innovation, however, would likely be controversial. Absent such a measure, the government might well be unwilling to invest the significant resources that might be necessary to establish liability in a complex products liability case.<sup>302</sup>

In any event, excluding the private bar from the enforcement of product safety standards would raise issues apart from the question of resources.<sup>303</sup> On

298. Cf. McGarity, *supra* note 44, at 564 (noting that "the reality of very limited agency resources means that even those officials who are committed to seeking out and eliminating fraud are generally not able to do so").

299. As Michael Green noted in 1997, "The FDA is woefully underfunded for its mandate, which includes regulatory oversight of products that account for more than twenty-five percent of all American consumer purchases." Green, *supra* note 46, at 476.

300. Congress has enacted legislation requiring companies to pay a fee when they apply for approval of a new drug or biologic; the fees help to pay the costs of speedier FDA review. See Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, Title I, 106 Stat. 4491 (codified as amended at 21 U.S.C. §§ 379g, 379h (2000)).

301. A fee-shifting provision could provide, for example, that the government could recover the reasonable costs of a successful lawsuit. Such a provision could provide for either one-way or two-way fee-shifting. Currently, the Equal Access to Justice Act authorizes fee-shifting in favor of respondents in administrative adversary proceedings where the agency's position in bringing the proceeding was not substantially justified. 5 U.S.C. § 504(a)(1) (2000). However, most device makers, and probably all pharmaceutical companies, would be ineligible to receive fees under the Act because their net worth exceeds the Act's limitations. See *id.* § 504(b)(1)(B).

302. Cf. Herbert M. Kritzer, *From Litigators of Ordinary Cases to Litigators of Extraordinary Cases: Stratification of the Plaintiffs' Bar in the Twenty-First Century*, 51 DEPAUL L. REV. 219, 235 (2001) (noting, with respect to the plaintiffs' bar's involvement in state tobacco litigation, that "[s]tates turned to contingency fee arrangements as a way of eliminating their own risks of having to devote substantial dollars or other resources to the litigation").

303. Cf. 2 ALI REPORTERS' STUDY, *supra* note 114, at 86 ("Regulatory agency 'failure' may occur because of inadequate resources or on account of political or bureaucratic pressures. A system of privately initiated tort remedies, administered through the decentralized, general purpose

one hand, the agency might fail to initiate proceedings that should be brought. Enforcement personnel within the FDA might not always be quick to question the FDA's own prior safety determinations—yet that questioning would be desirable in some instances, when postmarketing experience discloses a previously unknown safety issue. On the other hand, agency personnel would not have the direct personal stake in the outcome that leads plaintiffs' lawyers to be careful in selecting which cases to take: Agency personnel would be paid their salary whether or not a given enforcement action resulted in a victory for the agency.

By contrast, the private plaintiffs' lawyers who would litigate actions in the other two models would have a strong incentive to screen cases, because they would recover fees only if they obtained a judgment or settlement. The more expertise a plaintiff's lawyer possesses in the field of medical products liability, the more likely the lawyer is to assess accurately a claim's potential for success. Not only has the plaintiffs' bar generally become more specialized in recent years,<sup>304</sup> but the firms handling complex, high-end cases have increased both their expertise and their resources.<sup>305</sup> Such firms, when they specialize in products liability cases, are likely to possess high concentrations of both procedural expertise and substantive medical expertise.<sup>306</sup> They also have the resources to invest in medical and scientific experts and to commission the type of data-mining projects that could disclose emerging safety issues.<sup>307</sup>

A system that employed *qui tam* suits to litigate product safety issues might help to ensure that cases were litigated by firms that possessed the necessary expertise.<sup>308</sup> Individual plaintiffs may fail to select the most experienced counsel

---

court system, can serve as a corrective for these shortcomings.”).

304. See, e.g., John P. Heinz et al., *The Changing Character of Lawyers' Work: Chicago in 1975 and 1995*, 32 LAW & SOC'Y REV. 751, 753-54, 761-62 (1998) (reporting, based on a mid-1990s survey of Chicago lawyers, that lawyer specialization “appears to have increased substantially,” especially among plaintiffs' personal injury lawyers).

305. See Nagareda, *supra* note 15, at 319-20.

306. See Kritzer, *supra* note 302, at 231 (“Law firms that litigate huge, complex cases, such as tobacco, breast implant, and the like, require staff and financial resources beyond the scale of the traditional plaintiffs' firms.”); *id.* at 232 (noting the emergence of “repeat player” plaintiffs' firms with “the ability to bring to bear substantial legal effort and to deal with the cost of extended, monster-scale litigation”).

307. Although data mining could provide a powerful tool to identify emerging issues, there is some question whether the private bar would have access to useful databases, in the light of patient privacy concerns. It seems likely, however, that there will exist at least some relevant databases that are available for private analysis.

308. Defendants, as repeat players in products liability litigation, are likely to retain lawyers with substantive and procedural expertise. See Susan Brodie Haire et al., *Attorney Expertise*,



to represent them; though informal networks—such as referrals by generalists to specialist attorneys—may help to bridge the informational gap, some plaintiffs with valid claims may select less than expert representation.<sup>309</sup> By contrast, in a *qui tam* setting, a potential claim could attract more than one set of plaintiffs' attorneys, and the court could select among them based upon their resources and expertise.<sup>310</sup>

Another advantage of the *qui tam* mechanism is that it would provide an incentive for industry insiders to act upon information concerning safety problems: An insider possessing such information could bring a *qui tam* claim and share in the resulting recovery. Admittedly, there are other ways to provide incentives for the disclosure of such information. For example, Congress could provide a bounty for the provision of information that leads to a successful government penalty action.<sup>311</sup> However, some insiders might mistrust a reward system in which the availability of the reward would depend on the government's decision to litigate, and success in establishing the claim; such insiders might be more likely to come forward if they could bring suit themselves as *qui tam* relators.<sup>312</sup>

Policy considerations, then, suggest that the *qui tam*/hybrid scheme provides the best alternative for linking the litigation and regulatory systems. Considerations of cost and speed are inconclusive: Agency proceedings may be

*Litigant Success, and Judicial Decisionmaking in the U.S. Courts of Appeals*, 33 L. & SOC'Y REV. 667, 674-77 (1999) (reporting results of study that analyzed degrees of specialization of lead counsel for plaintiff and defendant in sample of products liability cases drawn from federal appellate opinions on Westlaw; study indicated that defendants' counsel tended to have more procedural experience, and somewhat more substantive expertise, than plaintiffs' counsel).

309. See *id.* at 668 ("Although the high stakes of products liability litigation has created a financial incentive for many plaintiffs' lawyers and firms to orient their practice in this area, individual plaintiffs may not be capable of making informed judgments when selecting firms or attorneys best suited to represent their interests.").

310. See *supra* note 174 and accompanying text.

311. At least one such provision already exists. See 21 U.S.C. § 333(b)(5) (2000) (providing bounty for information leading to criminal convictions for violations of certain laws concerning sales of drug samples).

312. Such concerns supported Congress's provision of a *qui tam* mechanism in the FCA. As Evan Caminker has explained:

Congress determined that potential rewards alone would not provide sufficient incentive for disclosure; many potential informers are reluctant to come forward because they refuse to accept the 'personal and financial risk' involved absent any 'confidence in the Government's ability to remedy' the misconduct, a fear rectifiable only by allowing for participation in the litigation.

Caminker, *supra* note 159, at 351 (quoting S. REP. NO. 99-345, at 6-7, *reprinted in* 1986 U.S.C.C.A.N. 5266).

cheaper than hybrid proceedings, but the savings would likely result from streamlined procedures that would diminish the investigative power of the discovery process. Quality of decisionmaking favors the use of the hybrid system, because there are reasons to think that the federal courts could do a more reliable job of supervising discovery and assessing damages. Quality of advocacy weighs in favor of the *qui tam* mechanism, because the incentives and expertise of *qui tam* relators and their counsel could improve the investigation and presentation of potentially valid claims. Having thus suggested that the *qui tam*/hybrid system may be the best option for providing a structural connection between litigation and FDA decisionmaking, I proceed, in the next Part, to consider how such a mechanism would work.

### III. STRUCTURING A HYBRID SYSTEM

In this Part, I sketch in somewhat more detail the *qui tam*/hybrid option described above. A distinctive feature of the proposal is that a company would have the option to select the federal *qui tam* system at the time it submitted a product for FDA approval. Opting in would preempt state tort claims concerning the product; in return, the company would be required to submit to a rigorous set of federal products liability standards. In Section III.A, I describe the opt-in system; Section III.B considers ways in which the *qui tam* mechanism could improve postmarketing surveillance with respect to companies that opted in.

#### A. An Opt-In and a *Quid pro Quo*

A central feature of the proposed scheme is that a company would choose, when submitting a product for FDA approval, whether to opt in to the *parens patriae* system with respect to that product. By choosing to opt in, the company would disclaim any constitutional objections to the adjudicatory scheme described in Part II.<sup>313</sup> Companies' choices concerning the opt-in could also shed light on their true assessments of the jury system. In addition, the scheme offers a chance to obtain a *quid pro quo*: If the jury system imposes high uncertainty costs on companies, companies should be willing to opt in to the proposed scheme even if it broadens the range of situations in which some amount of compensation must be paid.

#### 1. Revealing Companies' Views About the Tort System

Many in the corporate sector are quick to complain about the tort system. Critics frequently assert that juries are incompetent to handle technical or

---

313. See *supra* note 268 and accompanying text.

scientific questions, that they favor plaintiffs, that they award excessive damages, and that their determinations are irrational and unpredictable. Such contentions loom large in the preemption debate: Lay juries, defendants assert, should not be permitted to second-guess the expert determinations made by the FDA. The proposal outlined here offers a chance to illuminate companies' perceptions of litigation risk.<sup>314</sup> Given the chance, will companies exchange exposure to the jury system for a scheme that subjects liability to expert agency determination and imposes scheduled damages assessed by a judge?

In this regard, the opt-in system would address one of the dilemmas of the preemption debate. On one hand, preemption is disfavored because it deprives plaintiffs of compensation and displaces state law in a traditional area of state regulation. On the other, defendants—and now the FDA—argue that without preemption, the threat of liability will deter innovation. The problem is that it is difficult to know when, and to what extent, preemption is necessary in order to promote innovation: Is it really true that the threat of state tort liability will cause Company X to exit a line of research? After all, companies may make such arguments—whether or not they are true—in an attempt to decrease their liability exposure.<sup>315</sup> Research and development decisionmaking is particularly hard to study because it centers on nonpublic information.<sup>316</sup> Moreover, numerous factors may influence the incentive effects of liability risk. New drug development occurs mostly within large pharmaceutical companies; while new

---

314. Of course, the criticisms of the civil justice system described in the text are highly contested. But if the concern is whether innovation will be deterred or promoted, policymakers may validly consider the industry's perception of litigation risk, whether or not that perception is accurate. See Steven Garber, *Product Liability, Punitive Damages, Business Decisions and Economic Outcomes*, 1998 WIS. L. REV. 237, 250-51 ("To dismiss misperception by company decisionmakers (as many do) as 'their problem' misses the key point: If misperception contributes to manufacturer decisions and economic outcomes that are socially undesirable, that is also *our* (i.e., society's) problem.").

The notion of "revealed preferences"—i.e., the theory that an actor's choices can reveal the actor's preferences—has been criticized. See, e.g., Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 76-80 (1995) (noting, among other things, that choices can be highly contextual). However, companies' choices concerning the opt-in system described in the text would accurately reveal their views concerning the precise question at issue in the preemption debate: the extent of the risk companies perceive to flow from the civil justice system.

315. See GARBER, *supra* note 96, at 3 n.2 (noting, with respect to "surveys of the business community," that "respondents . . . have incentives to exaggerate detrimental effects of liability and understate beneficial ones").

316. See *id.* at 142 ("Because innovation is so crucial to private performance, R&D strategies and activities are typically closely guarded secrets. As a result, very little systematic information about the innovative efforts of individual companies is publicly available.").

medical devices often are developed by smaller enterprises.<sup>317</sup> The effects of liability exposure on innovation are likely to vary depending on the type of product.<sup>318</sup>

My proposal would put the companies' assertions to the test. A business that chooses to remain subject to state tort law (rather than opting in to the federal liability system) would have a more difficult time establishing that state tort law deters it from societally useful innovations. Thus, for a company that fails to opt in to the federal liability system, there should be no preemption of state tort law. The proposal described here would offer a choice between state tort law (applied by juries) and a federal liability system (applied by an expert panel, the FDA, and a federal judge). Companies that did not opt in to the federal system would be subject to state law to a greater degree than they currently are, because there would be no preemption of state law claims. But they could not claim that they were deterred from innovating, unless they also argued that the compensation scheme provided in the opt-in system deterred innovation as well.<sup>319</sup> That, at least, would have the salutary effect of moving the debate away from complaints about jury incompetence and toward a focus on the appropriate balance between innovation and compensation. Accordingly, I turn next to a discussion of the shape of liability under the opt-in scheme.

---

317. *See id.* at 22 (noting that “diversified, and hence relatively large, R&D operations” have an edge in developing new drugs, while “smaller companies are a more typical source of innovation in medical devices”).

318. *See id.* at 144 (noting reports “that product liability has substantially discouraged innovation efforts in vaccines, contraceptives, and orphan drugs”).

319. Relevant judgments about litigation risk will be made by the company itself in some instances; in others, the judgments of liability insurers will be relevant as well. As Steven Garber has noted:

For some companies, some direct costs [of liability] are covered by commercial insurance. But the existence of commercial product liability insurance hardly makes direct liability costs irrelevant. Large companies tend to be self-insured (i.e., uninsured) for product liability. In addition, liability costs paid or reimbursed by insurance companies are costly to insured companies because adverse liability experience is likely to lead to higher insurance premiums—or lack of insurance coverage—in the future. Moreover, punitive damages payments are not insurable or are only partially recoverable in many states.

Garber, *supra* note 314, at 243-44. The opt-in mechanism described here would provide information concerning decisionmakers' views of the relative litigation risks of the state-law tort system and the opt-in system—whether the decisionmaker in question is the company itself or the company's liability insurer.

## 2. Broadening Compensation

From a procedural and institutional standpoint, the opt-in scheme would promise significant advantages to a potential defendant. Instead of multiple proceedings in various jurisdictions, the *parens patriae* proceeding would be a single action in a single federal district court.<sup>320</sup> In place of liability determinations under varying state tort doctrines, applied by lay juries and generalist judges, the *parens patriae* regime would employ a federal standard of liability applied by a specialist panel (with review by the FDA). The opt-in scheme thus would likely provide a significant reduction in litigation costs and could also promise both uniformity<sup>321</sup> and greater predictability.<sup>322</sup>

In return, the scheme could require companies that opted in to submit to more rigorous standards of liability than they might encounter under some state tort regimes. This Subsection sketches the possible outlines of such a liability framework. I do not attempt to show that the measures outlined here constitute optimal levels of liability for the opt-in scheme; rather, I use them to illustrate the notion that the opt-in scheme could impose somewhat more rigorous standards, relative to state tort law, without necessarily deterring innovation. The proof of this, of course, would come in the execution: If companies failed to opt in to the system, that could be a sign that the opt-in liability rules had overreached.

Like state tort law,<sup>323</sup> the opt-in system would impose strict liability for

320. The possibility that more than one *qui tam* relator might bring a particular claim is addressed above. See *supra* text accompanying notes 171-174.

321. Cf. GARBER, *supra* note 96, at 57 (noting that the tort system's "complexity and interjurisdictional variation in doctrine" contribute to the uncertainty faced by potential defendants).

322. Some potential defendants will also like the opt-in system because it eliminates the possibility of jury trials. Empirical research has rebutted many of the complaints about jury performance, and, indeed, has suggested that products liability defendants may fare no worse before juries than before judges. See Kevin M. Clermont & Theodore Eisenberg, *Trial by Jury or Judge: Transcending Empiricism*, 77 CORNELL L. REV. 1124, 1162 (1992) (examining data from federal court cases from 1979 to 1989 and finding that products liability plaintiffs have higher win rates in bench trials than in jury trials). Obviously, the win rates in bench trials and jury trials are affected by the mix of cases heard by judges and by juries, see *id.* at 1162-63, so that the differing win rates do not in themselves prove that juries are friendlier to defendants than judges are. However, the contrast does suggest that juries are not as credulous concerning plaintiffs' claims as critics of the tort system suggest. Nonetheless, corporate decisionmakers may still believe that jury trials are undesirable. See Clermont & Eisenberg, *supra* note 281, at 146 ("Despite years of research that rebuts stereotypes about juries, every day lawyers and policymakers act on the basis of those stereotypes.").

323. See, e.g., RESTATEMENT (THIRD) OF PRODUCTS LIABILITY, §§ 2(a), 6(b)(1) (1998) (imposing strict liability for manufacturing defects); *id.* § 6 cmt. a (noting that Section 6(b)(1) states a



manufacturing defects. This is uncontroversial, and (from the viewpoint of drug manufacturers), relatively inconsequential: The FDA tightly regulates manufacturing practices, and as a result, cases of manufacturing defects are rare in the prescription drug context.<sup>324</sup> (Manufacturing defects are, however, more common with respect to medical devices.<sup>325</sup>) A manufacturing defect defendant would be liable for medical costs, other costs of care, lost wages, and scheduled amounts for pain and suffering.

The treatment of design defects would be more significant, and here the use of the hybrid system could provide a significant benefit compared with ordinary litigation. As I have noted,<sup>326</sup> the courts are divided over the question of pharmaceutical design defects: The question is whether the FDA's risk-benefit determination (in approving a drug for marketing) should ever be second-guessed by courts in the light of later-surfaced information. The hybrid system could avoid this dilemma, by requiring the FDA itself to revisit its safety determination. The system could direct the FDA to apply the same risk-benefit standard it had employed during the premarketing approval phase,<sup>327</sup> but to update the analysis to take account of later-discovered information.<sup>328</sup> If the later-discovered

---

"traditional rule[']").

324. See 5 FRUMER & FRIEDMAN, *supra* note 102, § 50.03A[3], at 50-29 (noting that "prescription drugs are manufactured to stringent standards, overseen by the FDA"). Frumer and Friedman also note that manufacturing defects—to the extent that they occur—would often be difficult to prove, because the patient may consume all of the drug, and because other portions of the same batch "may be used up, contaminated, discarded or changed through age in such a way as to defy any meaningful scientific evaluation." *Id.* at 50-20 to 50-29.

325. See GARBER, *supra* note 96, at 39 ("Manufacturing defects seem relatively unimportant in the pharmaceutical industry, but they appear more important for medical devices."). The Shiley heart valve provides a notorious instance. See *id.* at 39 n.19.

326. See *supra* notes 99-104 and accompanying text.

327. See RISK MANAGEMENT REPORT, *supra* note 23, at 21-22 ("Although medical products are required to be safe, safety does not mean zero risk . . . . A *safe medical product* is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available.").

328. Alternatively, the opt-in system could impose a more stringent standard. For example, the FDA's Task Force on Risk Management noted that one reason why problems that surface in the postmarketing period can affect large numbers of people is that the product rollout may extend to many types of patients. "[I]f use of a new product were evaluated comparatively, the potential extent of injury from an unknown risk might be reduced because the product's initial postmarketing use could be limited to those patients who have been shown to experience a clear therapeutic benefit over an alternative product." *Id.* at 49. The FDA's premarketing review does not generally require a comparison of the product's safety and efficacy with those of competitor products. However, it might be possible to take comparative efficacy and safety into account *ex post*, in determining the appropriate extent of liability for damages when patients have been harmed by the product.

information altered the risk-benefit analysis to such a degree that the product should no longer be marketed, liability under a product defect theory would be appropriate. Damages could vary depending on when and how the relevant information came to light. If the product's riskiness was both unknown and unknowable at the time of sale, damages might be limited to medical expenses and cost of care up to a capped amount.<sup>329</sup> By contrast, if the relevant information could have been uncovered by the company had it been proactive in self-regulating with regard to safety, then damages could include uncapped medical expenses and cost of care, plus lost wages and scheduled amounts for pain and suffering.

In many instances, later-discovered information may not justify withdrawal of the product, but may require additional warnings. State tort law generally holds defendants liable for failure to warn of known or knowable risks.<sup>330</sup> If information that came to light after premarket approval were found to justify a warning, the opt-in system could impose liability as to claimants who were sold the product without that warning.<sup>331</sup> As with product defect claims, damages for failure to warn could vary depending on when the relevant information surfaced and whether a proactive, self-regulating company should have been aware of the need for the warning at the time of the sale.<sup>332</sup>

In all the categories discussed above, the determination could also take into

329. These damages could be considerable. For this reason, in cases where the product defect was unknowable at the time of sale, the statute could provide for a reduction in damages to the extent that such costs were covered by a collateral source such as health insurance.

330. See 5 FRUMER & FRIEDMAN, *supra* note 102, § 50.04[1], at 50-36 (“[I]n the vast majority of states, a manufacturer of prescription drugs has a duty to provide adequate warnings of only those dangers of which the manufacturer knew or should have known at the time of marketing . . .”).

331. Under the “learned intermediary” rule, a defendant usually satisfies its duty to warn by providing appropriate warnings to the health care provider rather than the patient. See GARBER, *supra* note 96, at 40. *But cf.* RESTATEMENT (THIRD) TORTS: PRODUCTS LIABILITY § 6 cmt. e (1998) (arguing that “direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider”). The opt-in system could adopt the “learned intermediary” rule, with appropriate exceptions. *But see* GARBER, *supra* note 96, at 43 (asserting that “liability costs are especially unpredictable where the learned intermediary rule is vulnerable to exception”).

332. Failure-to-warn cases would involve more than one type of causation question. As in all of the cases discussed in the text, the panel would make a general determination concerning whether the product causes the type of injuries at issue, and would provide guidelines for the court to use in determining whether a specific claimant's injuries were caused by the product. Failure-to-warn cases would also require a determination whether the provision of the warning would have prevented the harm to the claimant. This type of causation issue need not be referred to the panel; it could be decided, on a claim-by-claim basis, or with respect to particular classes of claims, by a special master under the direction of the district court.

account whether the company had engaged in misbehavior. Fraud on the FDA or other violations of FDA requirements could help to establish that the product was unsafe.<sup>333</sup> Moreover, in appropriate cases, fraud, serious violations of FDA requirements, or other egregious behavior could result in an award of punitive damages in addition to the compensatory damages discussed above.

A liability framework along the lines sketched above would extend the scope of liability, in some respects, beyond the boundaries set by some or all states. It would, for example, provide some level of compensatory damages in cases where the company could not yet have known of the relevant danger—such as when a safety issue first surfaces during the marketing of a new product.<sup>334</sup> And it would provide for design defect liability in cases where the FDA later concluded an approved product should be withdrawn from the market, though damages would vary depending on whether the risk was knowable at time of sale.<sup>335</sup>

On the other hand, the opt-in framework could promise increased predictability in damages awards. Pain and suffering damages, when available, would be calculated based on a matrix that took into account factors such as the type and extent of injury.<sup>336</sup> This approach would render non-economic damages awards under the opt-in system less variable than comparable awards in jury trials.<sup>337</sup> Though punitive damages would be available under both systems, the opt-in system would ensure that there would be no duplicative punitive awards.<sup>338</sup>

---

333. Under state tort law, “failure to comply with [FDA] regulations is often taken as evidence of negligence per se.” GARBER, *supra* note 96, at 43.

334. As discussed above, state tort law generally does not impose liability for risks that were not knowable at time of sale.

335. As noted above, some states consider all prescription drugs to be “unavoidably unsafe,” which in effect precludes design defect liability (though liability can still be imposed on other theories, such as failure-to-warn).

336. See Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling “Pain and Suffering,”* 83 NW. U. L. REV. 908, 939 (1989) (suggesting a matrix for non-economic damages determinations based on “the severity of injury, the injured person’s age, and the body part affected”).

337. Studies suggest that the non-economic components of jury awards may be more variable than the components that reflect economic damages (such as medical expenses). See *id.* at 937 tbl.3 (recounting results of study of personal injury jury verdicts in Kansas City and Florida in 1970s and 1980s); Shari Seidman Diamond et al., *Juror Judgments About Liability and Damages: Sources of Variability and Ways To Increase Consistency*, 48 DEPAUL L. REV. 301, 317 (1998) (describing results of jury experiment).

338. An ALI Reporters’ Study explained the issues that arise from the possibility of punitive awards in product liability mass torts:

If liability for punitive damages can be established for *any* of the resulting tort claims, then such an award should be available for *all* the claims arising out of the single

The opt-in system would also constrain awards, relative to the largest awards in the jury system. This would be true, for example, when awards in the opt-in system were compared to jury awards that include large components of pain and suffering.<sup>339</sup> It should be noted that media coverage tends to overplay such large awards and to underemphasize the extent to which they are reduced post-verdict by settlement or judicial review.<sup>340</sup> Nonetheless, the highest awards under the opt-in system would likely fail to approach the highest awards that might occur in the jury system.

From the claimants' perspective, these changes might not have as great an effect on net compensation as might at first appear. Plaintiffs' net recoveries in the tort system are substantially reduced by costs and contingent attorney fees; in the opt-in system, by contrast, successful relators would recover a reasonable attorney's fee as a separate element of damages.<sup>341</sup> From the potential

corporate misdeed. Yet the consequence is that beyond . . . compensatory damages . . . the firm will be penalized again and again for a single wrongful judgment or action . . . . [S]ubstantial payments for the earlier punitive awards may strip the firm of its insurance coverage and assets, thus endangering the ability of later claimants to [obtain] compensatory redress.

2 ALI REPORTERS' STUDY, *supra* note 114, at 260-61. As this passage indicates, the possibility of multiple punitive awards for the same course of conduct has caused concern. It is far less clear, however, that the actual incidence of punitive awards poses a substantial problem. *See supra* note 11. Nonetheless, to the extent that industry decisionmakers fear the potential for multiple punitive awards, the opt-in system could provide a valuable alternative.

339. In the case of pain and suffering damages, the difference would result from the fact that, in the opt-in system, such damages would be scheduled. With respect to some products, a difference might also arise between the aggregate punitive damages awarded under each system. Empirical research suggests that juries do not differ substantially from judges in awarding punitive damages:

Juries and judges award punitive damages at about the same rate, and their punitive awards bear about the same relation to their compensatory awards. Jury punitive awards have a bit more spread than judge awards, but the effect is not robust and leads to few jury punitive awards outside the range of what judges are expected to award.

Eisenberg et al., *supra* note 11, at 780 app. tbl.1 (reporting results of study of data from trials in 1996 in selected state courts). (As the authors note, the conclusions that can be drawn from these findings are limited by the fact that case characteristics may differ as between bench trials and jury trials; but still the data are suggestive. *See id.* at 746.) However, a difference could arise from the fact that, under the opt-in system, punitives would be determined and awarded, if at all, in a single action, rather than (potentially) in multiple actions concerning the same product. *See supra* note 338 and accompanying text.

340. *See, e.g.*, GARBER, *supra* note 96, at 60 ("[M]ass media seem to provide more complete coverage of plaintiff victories and large and punitive awards than defendant victories, small awards, damages reduced by the judge, or cases overturned on appeal.").

341. *Cf.* 2 ALI REPORTERS' STUDY, *supra* note 114, at 229 (warning that limits on pain and

defendant's perspective, however, even if the mean payout under the opt-in system (taking attorneys' fees into account) were equivalent to that under the tort system, the opt-in system would eliminate the possibility of truly high-end awards. This feature might have significant appeal for decisionmakers to the extent that their deliberations focus on the magnitude of "worst case scenarios" rather than on their probability.<sup>342</sup>

As this discussion suggests, the opt-in system might prove attractive to potential defendants while still serving compensatory (and, where appropriate, punitive) goals. As I explain in the next Subsection, the system could also improve the FDA's ability to conduct postmarketing surveillance with respect to the products of companies that opted in.

### *B. Improving Postmarketing Surveillance*

As discussed in Part I, the FDA's postmarketing surveillance of drugs and devices is less than optimally rigorous. Though companies must report adverse events, the data are reported in a summary format that may not disclose all relevant information. The FDA lacks the resources to adequately analyze postmarketing data and lacks sufficient ability to obtain further information from companies when needed. In this Section, I discuss ways in which a *parens patriae* litigation system could supplement the FDA's scarce postmarketing surveillance resources. The system could help FDA regulators to focus their investigative resources, by flagging emerging safety problems. Information unearthed during discovery could provide insights that otherwise might not reach the FDA. And for claims that survived summary judgment, the referral of safety and causation issues to the panel would provide the FDA with a formal occasion

---

suffering damages should "be adopted only as part of a multifaceted tort reform that would also make the successful plaintiff's attorney fees an independently compensable head of damages").

342. Two studies of corporate executives in the 1970s and 1980s found that the executives based their decisions more on "the magnitudes of possible bad outcomes" than on their probability. James G. March & Zur Shapira, *Managerial Perspectives on Risk and Risk Taking*, 33 MGMT. SCI. 1404, 1407 (1987). Thus, for example, in one study, eighty percent of the executives "asked for estimates of the 'worst outcome' or the 'maximum loss'" when evaluating a possible course of action. *Id.* The focus on the magnitude rather than the probability of the worst-case scenario "leads to a propensity to accept greater risk (in the sense of variance) when the probability distribution of possible outcomes is relatively rectangular than where there are relatively long tails." *Id.* at 1411; see also GARBER, *supra* note 96, at 71-72 (employing March and Shapira's findings to assess the likely effects of products liability exposure on industrial decisionmaking and concluding that "the possibility of extremely bad outcomes is particularly salient in the decision process"); cf. Sage, *supra* note 46, at 1004 (noting that "managerial risk aversion exists regardless of the availability of insurance").



for taking a hard look at its prior approval decision.

### *1. Providing an Early Alert System*

When a *qui tam* relator filed a *parens patriae* suit, it would be required to serve the complaint and related information on the government. In addition to providing the government with an opportunity to take over the litigation, this notice would provide the FDA with a systematic source of information concerning potential problems that are ripening into litigation. In instances where a safety problem has been publicly discussed prior to suit, the filing would not provide the first indication of a problem; in other instances, as where the *qui tam* relator is a former employee who sues based on nonpublic information, the filing might provide the first concrete evidence of a safety issue. In either event, the filing would flag the problem as potentially significant, and it would alert the FDA to the need to monitor the litigation so that regulators could promptly assess information uncovered through discovery.

### *2. Using Civil Discovery To Supplement Reporting*

Discovery in the *qui tam* litigation may uncover information that otherwise would not make its way to the FDA.<sup>343</sup> A *qui tam* relator can use the civil discovery tools to obtain information that would not appear in reports submitted to the FDA.<sup>344</sup> Though private tort suits may already uncover such information, the phenomenon of “secret settlements” may limit the extent to which information obtained in private suits reaches the FDA; in *qui tam* suits, by contrast, the FDA automatically would have access to the fruits of the discovery process.

Some critics have complained that the FDA’s information-gathering capabilities are largely passive.<sup>345</sup> “[T]he FDA lacks the general subpoena power

---

343. Cf. Green, *supra* note 46, at 499 (noting that drug manufacturers’ reporting of adverse events “has been less than perfect,” and that “[s]ome notable examples of flagrant manufacturer disregard for [the reporting] requirement have been documented, sometimes as the result of a tort suit”).

344. Cf. McGarity, *supra* note 44, at 571 (“Private attorneys are adept at uncovering evidence of fraud and misrepresentation in the discovery that precedes common law trials, and they are willing to spend the resources necessary to copy and organize documents, take depositions, and fight the company’s efforts to resist discovery.”).

345. Cf. Rabin, *supra* note 12, at 2069 (“Even in the case of a comprehensive regulatory regime like FDA certification of new drugs, the agency process is noninvasive: the burden is on the company to produce evidence in support of its new drug application, and the agency does not conduct its own testing and experimentation.”).

that other agencies have, and therefore, in most instances cannot compel the disclosure of information about product risks.”<sup>346</sup> Reporting requirements provide the FDA with basic information concerning adverse events (so long as companies comply with their reporting obligations). But discovery in a *qui tam* suit could shed light on problems that might not be as readily apparent in the summary reports. For example, a lawyer for the plaintiffs in a suit involving Paxil asserts that “court-ordered discovery allowed her to see raw data on safety and efficacy, while the FDA saw only the completed write-ups,” and that discovery also produced “the company’s internal communications about how to approach the agency, which the FDA never saw.”<sup>347</sup>

In addition to obtaining documents that would not be turned over in routine reporting to the FDA, a *qui tam* relator could follow up on promising avenues by deposing company employees. In the Bjork-Shiley heart valve litigation, for example, employee depositions revealed that workers “disguised cracks in defective valves,” and document discovery unearthed a plant supervisor’s memorandum that “complain[ed] of a company policy of disguising cracked valves as intact [and stated] ‘I feel we are hiding our most serious defect.’”<sup>348</sup> Other employees may have equally pertinent information; for instance, sales representatives who are responsible for marketing a product to physicians may often have early warning of safety issues with the product.<sup>349</sup>

---

346. Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1386 (1994). Schwartz notes that the FDA does have “power to demand documents where statutory provisions specifically provide, such as those governing factory inspections and new drug approvals,” and that companies may “disclose information voluntarily to the FDA to create good relations or to avoid an enforcement action.” *Id.* at 1386 n.177.

347. Gary Young, *FDA Strategy Would Pre-empt Tort Suits: Does It Close Off Vital Drug Data?*, NAT’L L.J., Mar. 1, 2004, at 1, 12 (discussing statements by Karen Barth Menzies); see also Gina Kolata, *Questions Raised on Ability of F.D.A. To Protect Public*, N.Y. TIMES, Jan. 26, 1992, § 1, at 1 (“In the case of Halcion, critics who have examined case report forms in connection with a lawsuit against Upjohn charge that the company left out information about adverse reactions reported on those forms when it prepared its data analyses for the F.D.A. Upjohn denies the charges . . .”). Likewise, discovery in the Vioxx litigation has apparently brought to light documents that bear upon Merck’s knowledge of safety problems with the drug. See Harris, *supra* note 70.

348. Gina Kolata, *Manufacturer of Faulty Heart Valve Barred Data on Dangers*, F.D.A. SAYS, N.Y. TIMES, Mar. 21, 1992, § 1, at 50.

349. See Kit R. Roane, *Replacement Parts: How the FDA Allows Faulty, and Sometimes Dangerous, Medical Devices onto the Market*, U.S. NEWS & WORLD REP., July 29, 2002, at 57, 59 (describing instances in which sales representatives became aware of concerns about product safety). “Direct contact between physicians (and other health-care professionals) and sales representatives of the companies is often the primary form of sales promotion,” though other methods include ads in medical publications, mailings to physicians, and direct-to-consumer ad

*Parens patriae* suits will also provide a more effective means of putting information uncovered during discovery into the hands of the FDA. When discovery in private civil suits yields information relevant to product safety, protective orders may sometimes prevent the plaintiffs' lawyers from sharing that information with the FDA.<sup>350</sup> Defendants that settle such cases may be able to obtain a return of damaging discovery materials and a court order that the terms of settlement remain confidential.<sup>351</sup> Plaintiffs may accede to such secrecy provisions in return for a higher settlement payment.<sup>352</sup> Commentators have raised concerns that secrecy provisions may prevent the disclosure to the FDA of

---

campaigns. GARBER, *supra* note 96, at 21; *see also* ANGELL, *supra* note 47, at 127 ("Drug reps are allowed to attend medical conferences, may be invited into operating and procedure rooms, and sometimes are even present when physicians examine patients . . .").

350. *See* Kolata, *supra* note 348 (discussing protective order in case involving Bjork-Shiley heart valve and stating that company did not disclose to the FDA certain information, covered by the protective order, until the suit was dismissed); Kolata, *supra* note 347 ("[T]he data that caused the Commissioner . . . to ban [silicone breast] implants this month pending a review of their safety . . . were disclosed to trial lawyers eight years ago, but the [FDA] learned about them only recently because a court agreement had kept them confidential.").

351. *See* Joseph F. Anderson Jr., *Hidden from the Public by Order of the Court: The Case Against Government-Enforced Secrecy*, 55 S.C. L. REV. 711, 713-14 (2004) (describing aspects of secret settlements). As Judge Weinstein has explained, damaging discovery material can include:

"smoking gun" documents that indicate defendants knew of the danger but suppressed the information. Oral material obtained in depositions is also often highly useful to plaintiffs and devastating to defendants. Documents showing cover-ups or early knowledge by defendants of defects can lead to billions of dollars in punitive damages as well as extensive liability for ordinary damages, so there is strong reason for defendants to try to keep them secret.

Jack B. Weinstein, *Ethical Dilemmas in Mass Tort Litigation*, 88 NW. U. L. REV. 469, 512 (1994). Chief Judge Anderson notes that although the parties could reach a secrecy agreement without involving the court, defendants often "want the judge's signature, and the corresponding contempt power of the court, to legitimize their conduct and to have assurance that a violation will be summarily dealt with by the court." Anderson, *supra*, at 732.

Secret settlements are controversial. *Compare, e.g.,* Susan P. Koniak, *Are Agreements To Keep Secret Information Learned in Discovery Legal, Illegal, or Something in Between?*, 30 HOFSTRA L. REV. 783, 787 (2002) ("[A]ny legal regime that facilitates the keeping of secrets as lethal as the secrets Firestone was allowed to keep [concerning defective tires] may be a legal regime in need of serious repair. Certainly, the public is likely to feel that way . . ."), *with* Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 HARV. L. REV. 427, 431-32 (1991) (arguing that "promoting increased public access to information by restricting the discretion of the courts to protect confidential information is ill-advised").

352. *See* Anderson, *supra* note 351, at 731 (noting statements by "some plaintiffs' lawyers . . . that court-ordered secrecy gives them the opportunity to leverage a little more money out of the defendant at settlement time").

information concerning product safety.<sup>353</sup> In a *parens patriae* suit, by contrast, the FDA would have the right to review all information made available in discovery; the statutory framework could require that any protective order in the case provide the FDA's lawyers with the same status, under the protective order, as the lawyer for the *qui tam* relator.

### 3. Revisiting FDA Approval in Light of Later Information

In addition to uncovering or highlighting information on which the FDA may not previously have focused, the litigation process would provide a formal occasion for the FDA to revisit its prior safety assessments. A referral from the district court in a *qui tam* suit<sup>354</sup> would prompt an advisory panel to evaluate the issues of safety and causation in the light of the information developed during discovery. The FDA would then be required to review the panel's findings and would be aided in its review both by the parties' presentation of the issues and by the panel's views. Obviously, the FDA could revisit its safety determinations in any event. But the *qui tam* litigation could enhance the record on which the FDA based its reevaluation and could provide added incentives for the FDA to take a harder look at a questionable product.<sup>355</sup> In addition to answering the questions referred by the district court, the FDA would also have the opportunity to consider regulatory action concerning the product. The agency could require labeling changes, or—in extreme cases—direct the company to pull the product from the market.

## CONCLUSION

In sum, the system described in Part III could offer benefits. In addition to providing expert agency views on questions of product safety and causation, it

---

353. See Dorothy J. Clarke, *Court Secrecy and the Food and Drug Administration: A Regulatory Alternative to Restricting Secrecy Orders in Product Liability Litigation Involving FDA-Regulated Products*, 49 FOOD & DRUG L.J. 109, 111 (1994) (advocating amendment of the FDCA "to require drug and device manufacturers to submit information to the FDA regarding product liability litigation and settlements").

354. Such referrals would not cause undue inconvenience for the FDA, because they would only occur in cases where the relator successfully resisted the defendant's summary judgment motion. Because summary judgment would be granted unless the relator showed either a violation of existing FDA requirements or the existence of material information that the FDA had not previously considered, the summary judgment stage would screen out claims that did not merit consideration by the FDA.

355. See GARBNER, *supra* note 96, at 36 (noting that "[n]ew information and publicity [generated by products liability suits] can generate substantial pressure on the FDA to reevaluate its previous decisions").

could shed new light on companies' true views of the tort system and could preserve litigation's role in generating information on product safety. Potentially, the system could broaden the availability of compensation for persons injured by a medical product manufactured by a company that had opted in.<sup>356</sup>

Would that system be preferable to the status quo? The answer depends largely on one's view of the civil jury's capabilities. If juries truly are irremediably ill-suited to the task of assessing product safety and causation, then the *qui tam* system would provide a benefit by sending those issues to the FDA. As I have noted, however, commentators are divided in their assessment of the jury's capacities.<sup>357</sup> Moreover, it is possible to improve the performance of judges and juries within the current tort system<sup>358</sup>—an approach that holds the promise of addressing the critiques of the current tort system without embarking on radical systemic change.<sup>359</sup>

Equally important, the aim of obtaining expert agency resolution of products liability questions should be balanced against the risk of agency ineffectiveness or capture.<sup>360</sup> It should be readily apparent from the discussion above that in

356. However, the details of the compensation model adopted for the opt-in system would be key: If the opt-in system simply tracked the remedies available under current tort doctrine (rather than providing broader compensation), the chance to obtain a quid pro quo from the companies that opted in would be squandered.

357. See *supra* notes 9-11 and accompanying text.

358. Measures such as crafting better jury instructions, providing those instructions before as well as after the presentation of evidence, permitting jurors to take notes and submit questions to witnesses, and permitting interim arguments by lawyers during a complex trial may improve juror comprehension and performance. The presentation of expert testimony could be improved in appropriate cases by directing opposing sides' experts to testify back-to-back or by including testimony from a nonpartisan expert. Judges could provide juries with better guidance on assessing noneconomic damages, and could engage in more searching review of awards of such damages. And improved judicial training could better enable judges to perform all these tasks.

359. Cf. Rabin, *supra* note 12, at 2067 (raising "the question whether . . . institutional reforms of the tort process offer promise of addressing satisfactorily the criticisms of those who would displace tort in cases where scientific evidence is in play and a regulatory agency has independently assessed the risks associated with a product").

360. Other costs should also be considered. The *qui tam* system would in effect require aggregate determination of all covered products liability claims, thus eliminating the ability of many claimants to control the presentation of their claims. (Though aggregation would occur in many instances under the existing system, it would not always be necessary.)

Because the *qui tam* mechanism would create a special procedure for liability claims concerning FDA-regulated medical products, a question of boundaries would arise: What should be done with non-products liability claims arising from the same set of facts? For example, many failure-to-warn cases may also include malpractice claims against a health care provider. See, e.g., *Marks v. Ohmeda, Inc.*, 871 So. 2d 1148, 1151, 1156 (La. Ct. App. 2004) (sustaining judgment



order safely to privilege the agency's views on safety and causation, it will be necessary to ensure that those views are accurate and free of improper bias.<sup>361</sup> Recent events have underscored the difficulties with the FDA's current postmarketing surveillance system: Resource constraints, and possibly an unwillingness to question prior determinations of product safety, have impaired the FDA's ability to respond to emerging problems. Those difficulties would also plague any system that attempted to rely on the FDA to resolve retrospective liability questions. Proposals for the creation of an independent postmarketing surveillance agency might help to address this issue: If Congress were to create and adequately fund such an agency, and protect it from pressure by the FDA and by stakeholders, the independent agency might be able both to monitor product safety and to resolve appropriately safety and causation issues referred to it by a court. If Congress does not create an independent safety monitor, however, recent experience provides strong reason to question the wisdom of giving the FDA (as currently structured and funded) and its advisory panels (as currently staffed) a dispositive role in products liability actions.

This Article, accordingly, has failed to demonstrate that the hybrid system

---

against manufacturer of anesthetic and anesthesia machine, in failure-to-warn case that also involved malpractice claims against hospital and nurse anesthetist); *see also* RISK MANAGEMENT REPORT, *supra* note 23, at 26 (noting that “[s]ubstantial numbers of injuries and deaths occur annually” due to “incorrect administration of the prescribed product or incorrect operation or placement of a medical device”). Such malpractice claims generally would raise issues specific to the particular claimant and physician, and would be unsuitable for resolution within the *qui tam* system (which would focus on aggregate determination of the products liability issues). Thus, any benefits of the new system would be offset to some degree by the costs of parallel litigation.

361. Richard Nagareda has suggested that one advantage of referral to the agency is that the agency—unlike a jury—is politically accountable for its decisions. *See* Nagareda, *supra* note 15, at 299 (“Although agencies have long been considered repositories of technical expertise, commentators have neglected an equally powerful justification for agency involvement in the mass tort area: the political accountability of such bodies.”). As he argues, “[t]he conditions of scientific uncertainty that plague the handling of [mass torts] within the tort system cry out for the application of political judgment and deliberation through administrative channels in a manner susceptible to public scrutiny.” *Id.* at 313. The downside of agency accountability, however, is the potential for bias in favor of the regulated industry. Nagareda notes that “the highly concentrated interests typified by regulated industries . . . may be better positioned to sway a single regulatory agency at the federal level than to exert influence over the multitude of courts within which lawsuits would proceed in the tort system.” *Id.* at 364. He argues, however, that in the context of a referral to the agency of issues raised in mass tort litigation, the high-profile nature of the dispute and the existence of injured victims could counterbalance any tilt in favor of industry. *See id.* (“Agency action in the aftermath of thousands of individual tort suits—so many as to call for consolidation of litigation within the federal courts by the MDL Panel—is far less susceptible to influence by industry.”).

considered here is preferable to the status quo (or to less drastic options for reform). But it has shown that the *qui tam* system would be preferable to preemption. By privileging FDA determinations on safety and causation, the *qui tam* system would address preemption advocates' central criticisms of the current tort system. But unlike preemption, the *qui tam* system would address those criticisms while preserving some compensatory and monitoring role for litigation. Where preemption advocates tend to accept uncritically the industry's contention that the specter of tort liability chills innovation, the *qui tam* system would provide a means for measuring that contention against companies' actual choices concerning the opt-in. And where preemption would remove entirely the role of the states in regulating product safety, the *qui tam* proposal would displace that role only in instances where the manufacturer opted in to the *qui tam* system with respect to the relevant product.

Thus, this Article establishes that advocates of preemption who cast the debate in binary terms have failed to address the full range of options. Those advocates should be required to carry the burden of demonstrating the need for change, but they also should be required to show that, if change is warranted, preemption is the best choice. As this Article illustrates, a range of options short of preemption would address the asserted defects in the tort system without eliminating the ability to hold companies responsible for harm caused by safety problems with medical products.